UNITED STATES DISTRICT COURT
FOR DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, and the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN, the DISTRICT OF COLUMBIA, *ex rel.* ADAM WITKIN, Plaintiffs, vs. MEDTRONIC, INC. and MEDTRONIC MINIMED, INC., Defendants.	No. 1:11-cv-01790-DPW Judge Douglas P. Woodlock

AMENDED COMPLAINT

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Qui tam plaintiff and Relator Adam Witkin, on behalf of the United States, the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia (collectively "the States"), for his Complaint against defendants Medtronic, Inc. and Medtronic MiniMed, Inc. (collectively "Medtronic" or "Defendants"), alleges as follows.

INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the States arising from conduct of the Defendants which caused the submission of false claims to federal and state healthcare programs ("government healthcare programs") in violation of the False Claims Act, 31 U.S.C. §§ 3729–33, and the False Claims Acts of the above-named States. Mr. Witkin also brings claims on behalf of himself under the federal False Claims Act and state law for damages resulting from Medtronic's unlawful retaliation against him for engaging in protected conduct.

2. Medtronic, the largest medical device manufacturer, has used illegal incentives and promotions to market and sell devices for the treatment and management of diabetes ("diabetes devices"). These illegal practices are deployed throughout Medtronic's national sales force, and are designed to improperly incentivize the prescribing and purchasing of Medtronic products, including insulin pumps and pump accessories, to people with diabetes. Many of these patients are government

program beneficiaries.

3. Sales of insulin pumps and pump accessories are the largest source of revenue for Medtronic's Diabetes Division, which had $1.48 billion in revenue in FY 2012. In that same year, at least half of the 26 million Americans with diabetes were government healthcare program beneficiaries.

4. Medtronic's clear corporate strategy is to expand the reach of patients on its pump, without regard to whether those patients are appropriate for pump therapy. Medtronic's traditional market for pump sales was limited Type 1 diabetics and a small set of Type 2 diabetics with extreme forms of insulin-resistance, a small and relatively static part of the diabetic population eligible for Medicare coverage for pump therapy.

5. Medtronic identified that it could increase sales by expanding the use of the pump to new users, primarily the growing number of Type 2 patients and pediatric patients. Thus, notwithstanding the express conditions of government healthcare payment, Medtronic devised a variety of schemes to get around Medicare's coverage limitations and secure sales.

6. Thus, in order to expand into new markets and drive increased utilization of its products, Medtronic offers and pays physicians a range of inducements to order insulin pumps and other Medtronic products for their patients, including, among others, free nursing and case management services, opportunities for additional billing at reduced effort and expense to the physician, above fair-market-value payments for training, and other paid incentives.

7. Medtronic sales personnel present these inducements to providers as an economic package, for the purpose of securing Medtronic referrals from each targeted

provider. At many practices, and as required by corporate sales policy, Medtronic sets itself up as a "clinic" at that provider's practice, where its own sales representatives regularly hold themselves out as clinical professionals within in the provider's offices. Medtronic's sales representatives interact with the doctor's patients and perform medical procedures, all for the purpose of inducing the physicians to convert their patients to Medtronic insulin pumps.

8. In addition to illegal inducements, Medtronic engages in schemes to mislead providers regarding the reasonableness and necessity of the pump for use by government healthcare beneficiaries.

9. Medtronic directs it sales force to make material misrepresentations regarding the eligibility of Type 2 pump patients for pump therapy in order to induce more sales.

10. Medtronic also directs it sales force to make material misrepresentations regarding the safe and effective use of the pump with high-potency insulin (U-500) for Type 2 patients. The use of the pump with U-500 is off-label, for both the drug and the device, and is unsupported by clinical evidence of safety and efficacy. Medtronic's misrepresentations not only illegally induce use of the pump with the U-500 insulin, but cause significant health risks for patients.

11. Medtronic also directs it sales force to make material misrepresentations regarding the safe and effective use of the integrated adult insulin pump for use by pediatric patients. The use of the integrated adult pump for pediatric patients is off-label, as the integrated adult pump is not approved by the FDA for use in patients younger than 18. Moreover, the FDA approved a different Medtronic pump with greater safety

measures for use by pediatric patients, but Medtronic continues to sell the integrated adult pump to pediatric patients. Medtronic also promotes its integrated adult insulin pump for use by pediatric patients younger than 7 years, even though there is no integrated pump approved for that age group.

12. Medtronic also implemented a scheme to cause patients to order insulin pump replacement models before they are needed, and to falsify the justification submitted to government insurers in order to obtain reimbursement for these devices.

13. Every claim to government healthcare programs for an item or service resulting from these illegal inducements and promotional practices constitutes a false and fraudulent claim for payment under the federal and state False Claims Acts.

14. Based on these provisions and the provisions of the State false claims act statutes, *qui tam* plaintiff and relator Adam Witkin seeks to recover all available damages, civil penalties, and other relief for federal and state violations alleged herein, in every jurisdiction to which Medtronic's misconduct has extended.

15. In addition, Mr. Witkin seeks in this action to recover damages resulting from Medtronic's retaliation and discrimination against him for actions he took to stop Medtronic's fraud and other misconduct.

PARTIES

I. Plaintiffs.

1. *Qui tam* plaintiff-relator Adam Witkin ("Relator") is a resident of the State of Oregon. He was employed by Medtronic from November of 2004 until his retaliatory termination on February 28, 2011. Relator worked within the Diabetes Division of Medtronic, and held the position of Territory Manager and then Senior Territory

Manager for the Eugene Territory, which covers most of Oregon other than Portland. In that capacity, Mr. Witkin was responsible for the sale of Medtronic's medical devices for the treatment and management of diabetes. He received an MBA in May 2007 and a Masters in Strategic Management in August 2008, all while working full-time. In 2007, Relator was selected to Medtronic's President's Club, which recognizes top sales performers. In 2010, in addition to his normal job responsibilities as Senior Territory Manager, Relator was a National Field Trainer for Medtronic. By the time of his retaliatory termination in 2011, Mr. Witkin was one of the longest-tenured sales representatives within Medtronic's Diabetes Division. The facts alleged herein are based on Mr. Witkin's personal knowledge and on documents and information in his possession.

2. The Government plaintiffs in this lawsuit are the United States and the States of California, Colorado Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota Montana, Nevada, , New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia (collectively "the States").

II. Defendants.

3. Defendant Medtronic, Inc. is a Delaware corporation with its corporate headquarters and principal place of business in Minneapolis, Minnesota. It is a publicly held Fortune 200 company that develops, manufactures and markets medical devices. Medtronic promotes and sells its devices in this District, across the United States, and around the world. Medtronic had approximately $16.1 billion in revenue for fiscal year

2012, including approximately $1.48 billion in revenue from its Diabetes Operating Segment.

4. Defendant Medtronic MiniMed, Inc. ("MiniMed") is a Delaware corporation with its principal place of business in Northridge, California. MiniMed is a wholly-owned subsidiary of Medtronic, Inc. MiniMed manufactures, markets, and sells medical devices for the treatment and management of diabetes, including the devices that are the subject of this Complaint.

5. References in this complaint to "Medtronic" refer collectively to Medtronic, Inc. and Medtronic MiniMed, Inc.

JURISDICTION AND VENUE

6. Jurisdiction is based on 28 U.S.C. § 1331, 28 U.S.C. §1367, and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. § 3730. In addition, 31 U.S.C. § 3732(b) specifically confers jurisdiction on this Court over the state law claims asserted in this Complaint.

7. This Court has personal jurisdiction over defendants, pursuant to 31 U.S.C. § 3732(a), because that section authorizes nationwide service of process and because defendants have minimum contacts with the United States. Moreover, one or more of the defendants can be found in, reside in, and/or transact business in this judicial district.

8. Venue is proper, pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)–(c), because one or more of the defendants can be found in, reside in, and/or transact business in this judicial district. In addition, statutory violations, as alleged

herein, occurred in this judicial district.

9. The allegations of this Complaint have not been publicly disclosed in a criminal, civil, or administrative hearing, nor in any congressional, administrative, or General Accounting Office report, hearing, audit, or investigation, nor in the news media. Moreover, even if such a public disclosure had occurred, this Court would retain jurisdiction over this matter because Relator is the original source of the information upon which this Complaint is based, as that phrase in used in the False Claims Act and other laws at issue herein.

10. Relator provided disclosure of the allegations of this Complaint to the United States and the States prior to filing under the federal False Claims Act and state False Claims Acts, respectively.

RULE 9(b), FED. R. CIV. P. ALLEGATIONS

11. Much of the documentary evidence necessary to prove the allegations in this Complaint is in the exclusive possession of either the Defendants or the United States.

12. With respect to each allegation herein made upon information and belief, Relator has, based upon his knowledge, data, and experience, a reasoned factual basis to make the allegation but lacks complete details of it.

13. Relator is familiar with the policies and practices alleged herein as a result of his employment relationship with Medtronic and his personal observations of the Medtronic's scheme to improperly induce sales of its diabetic products, including without limitation through illegal incentives in violation of the Anti-Kickback and Stark Statutes and through illegal marketing of its products for off-label uses.

14. However, Relator does not have access to all of the information regarding the claims for payment submitted and caused to be submitted by Defendants. This information is in the exclusive possession and control of the Defendants and the United States or the States.

15. Defendants have caused to be submitted and, on information and belief, continue to cause submission of false claims to government healthcare programs for payment of items and services related to the sale of its diabetic products.

BACKGROUND

I. The False Claims Act.

16. The federal False Claims Act ("FCA") was originally enacted during the Civil War, and was substantially amended in 1986 and 2009. Congress enacted these amendments to enhance and modernize the government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the government's behalf.

17. The FCA provides that any person who presents or causes to be presented false or fraudulent claims for payment or approval to the United States Government; knowingly makes, uses, or causes to be made or used false records and statements to induce the Government to pay or approve false and fraudulent claims; or knowingly conceals, improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable for a civil penalty of up to $11,000 for

each such claim, plus three times the amount of the damages sustained by the Government.

18. A "claim" means any request or demand for money or property provided by the Government under one of its programs, such as Medicaid. 31 U.S.C. §§ 3729(b)(2). Claims made to the states are actionable under the FCA if the Government will reimburse the state for any portion of the claim. 31 U.S.C. § 3729(b)(2)(A).

19. The state FCAs contain comparable provisions for recovery of penalties and damages for any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval, or knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim. Relators bring claims under 28 state False Claims Acts and the False Claims Act of the District of Columbia, and the details of those provisions are provided in Counts II to XXXI.

20. The FCA's anti-retaliation provision, 31 U.S.C. § 3730(h), prohibits discrimination against a person in the terms and conditions of employment because of that person's efforts in furtherance of an action under that statute or efforts to stop one or more violations of the federal False Claims Act. A person retaliated against in violation of this section is entitled to reinstatement, double the amount of lost back pay, interest on the back pay, and special damages, including attorney fees and litigation costs.

21. Additionally, under the common law of Oregon, where relator was employed, an employer cannot terminate an at-will employee in retaliation for reporting to responsible authorities, internally or externally, his reasonable beliefs regarding the

violations of statutory or regulatory proscriptions at issue, which fulfill an important public duty. Under ORS § 659A.199, it is an unlawful employment practice for an employer to discharge or otherwise discriminate or retaliate against an employee for the reason that the employee has in good faith reported information that the employee believes is evidence of a violation of a state or federal law, rule or regulation. Moreover, under the common law of California, where Defendant Medtronic MiniMed, Inc. is headquartered and where Defendants manage their diabetes business and sales force, an employer cannot terminate an at-will employee in retaliation for his reports to responsible authorities internally within the company or externally of what the employee reasonably believes to be violations of statutory or regulatory proscriptions which implicate fundamental public policy.

II. The Anti-Kickback Statute.

22. The federal health care Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), arose out of a Congressional concern that payoffs to those who influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

23. The Anti-Kickback statute prohibits any person or entity from offering or providing "any remuneration" to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be

made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). Violation of the statute can subject the perpetrator to criminal and civil penalties, as well as exclusion from participation in federally-funded healthcare programs

24. The term "remuneration" includes anything of value, in whatever form, whether in cash or in kind, or offered directly or indirectly.

25. Payment of remuneration of any kind violates the statute if one of the purposes of the payment is to induce referrals.

26. Thus, the AKS prohibits medical device suppliers from offering to pay any remuneration, if one of the purposes of the remuneration is to induce physicians or others to recommend or use products paid in whole or in part by federal healthcare programs.

27. Each of the federally-funded health care programs requires every provider and supplier providing items and services for federal healthcare beneficiaries to promise and ensure compliance with the AKS as a material condition of payment of the resulting claims.

28. A claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim" for purposes of the False Claims Act. 42 U.S.C § 1320a-7b(g).

29. Giving a person the opportunity to earn money for referring patients may constitute an inducement under the AKS.

30. As stated by the Office of Inspector General of the Department of Health & Human Services ("OIG-HHS:

> Any time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer's product, the

> manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals. For example, if goods or services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician), or if items or services are sold to a physician at less than their fair market value, the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer.

OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23737 (May 5, 2003). OIG-HHS has made it clear that these principles apply equally to medical device suppliers:

> Manufacturers, providers, and suppliers of health care products and services frequently cultivate relationships with physicians in a position to generate business for them through a variety of practices, including gifts, entertainment, and personal services compensation arrangements. These activities have a high potential for fraud and abuse and, historically, have generated a substantial number of anti- kickback convictions. There is no substantive difference between remuneration from a pharmaceutical manufacturer or from a durable medical equipment or other supplier—if the remuneration is intended to generate any federal health care business, it potentially violates the anti-kickback statute.

Id.

31. The OIG also specifically identified as suspect arrangements where a manufacturer markets its products based on the difference in value between a provider's cost for an item or service and the reimbursement that the provider receives from government health insurance for that item or service. The OIG observed that "active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute." 68 Fed. Reg. at 23736-37.

32. Federal health care programs require every provider and supplier who provides items and services to federal healthcare beneficiaries to sign Provider/Supplier Agreements to establish their eligibility to seek reimbursement. Those agreements

certify that:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback Statute and the Stark law), and on the [provider/supplier's] compliance with all applicable conditions of participation in Medicare.

Form CMS-855.

33. The express language of the AKS, the certification of the provider/supplier agreements, and the repeated statements of the agency charged with administering the statute establish without question that compliance with the AKS is material to decision to pay claims for federal program beneficiaries.

34. Compliance with the AKS is a material condition of payment under all publicly-funded healthcare programs, including Medicare, Medicaid, CHAMPUS-TRICARE, CHAMPVA, Federal Health Benefit Program, and other federal and state health care programs (hereinafter referred to as "government healthcare programs").

III. The Stark Statute.

35. The Stark Statute, 42 U.S.C. § 1395nn, prohibits a physician from making referrals for certain "designated health services" payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies. The statute also prohibits the entity from billing Medicare for those referred services. The Center for Medicare and Medicaid ("CMS") has promulgated regulations interpreting the statute.

36. A financial relationship under the Stark laws includes arrangements involving any remuneration between a physician (or an immediate family member of

such physician) and an entity. 42 U.S.C. §§ 1395nn(a)(2)(B), (h)(1)(A).

37. A "referral" includes, among other things, "a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare…." 42 C.F.R § 411.351. A referring physician is defined as "a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made to another person or entity." *Id.*

38. Claims submitted in violation of the Stark Statute are ineligible for payment, and violate material conditions of payment of federal healthcare programs.

39. A claim for payment that is based on a violation of the Stark Statute constitutes a false claim under the FCA.

IV. FDA Regulation of Drugs and Medical Devices.

40. As explained further below, no drug nor medical device may be introduced into the market until and unless the FDA has approved it for commercial distribution for each of its intended uses.

41. Under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final step in a multi-year process of study and testing, and pharmaceutical concerns initiate the approval process by filing a New Drug Application ("NDA").

42. In 1976, Congress enacted the Medical Device Amendments ("MDA"), 21 U.S.C. § 360*c, et seq.*, to the FDCA, in order to synchronize FDA regulation of medical

devices with that of pharmaceutical products, and "to provide for the safety and effectiveness of medical devices intended for human use." Pub. L. No. 94-295, 90 Stat. 539, 539 (1976) (preamble). The MDA expanded the authority of the FDA to regulate medical devices, a business that has since grown exponentially into a multi-billion dollar industry, consisting of over 100,000 products in nearly 2,000 medical categories. The Center for Devices and Radiological Health ("CDRH") operates within the FDA to regulate medical devices.

43. Three routes exist for manufacturers of devices to obtain FDA approval. Most commonly, manufacturers seek "premarket approval" ("PMA") from the FDA, establishing, through extensive and lengthy review of data from clinical trials, bench and animal tests, "reasonable assurance" that the device is safe and effective for its intended use. 21 U.S.C. § 360*e*(d)(2).

44. To obtain PMA for a given device, FDA demands a complete report of all clinical and laboratory testing, a full statement of the components and design of the product, a description of the manufacturing process and quality controls, sample labeling instructions, and other detailed information. 21 U.S.C. § 360*e*(c)(1). This rigorous process requires the FDA to spend months reviewing and evaluating each such application, often in lengthy discussions with the manufacturer regarding safety and other concerns. For manufacturers like Medtronic, the process is necessarily prolonged, rigorous, and costly, ensuring that FDA releases for commercialization only those devices (and indicated uses) that can safely be utilized among vulnerable patient populations.

45. Two limited and exclusive exceptions to the PMA process exist for

manufacturers seeking to introduce their medical devices to consumers. First, a device can be sold if cleared by the FDA under the so-called 510(k) process, whereby the manufacturer can market and sell a device which is a "substantial equivalent" to a device already approved for the same use, where it certifies that the information submitted pursuant to the 510(k) process is "truthful and accurate." 21 U.S.C. § 360; 21 C.F.R. § 807.87(k). The manufacturer must obtain a clearance letter from FDA permitting it to market the device in question for indicated uses.

46. Second, devices judged to reflect innovative technology may be marketed under a restricted "investigational device exemption," or "IDE," for purposes of conducting investigations of that device. 21 U.S.C. § 360j(g); 21 C.F.R. § 812.1. None of Medtronic's diabetes devices at issue in this Complaint have been approved by the FDA under the IDE exception.

47. A medical device may not lawfully be marketed or promoted for a use not previously approved by the FDA under at least one of the three routes described above – the PMA process, the 510(k) process, or the IDE process.

48. The FDA does not approve a drug or a medical device for use *in general*. A drug or medical device is only approved on the basis of its intended use, or approved "indication," which must then be included in the product's labeling. 21 U.S.C. §§ 352, 355; 21 C.F.R. § 801.5. If the manufacturer wishes to market a new, unapproved use for its product, it must first obtain FDA approval (through one of the routes explained above) so that its labeling is changed to indicate the limits of any FDA approval of such additional or substitute uses. 21 C.F.R. § 807.81(a)(3).

49. "Off-label" refers to the promotion or use of an approved drug or device for

any purpose, or in any manner, other than what is stated in the product's labeling (*i.e*., what has been approved by the FDA as an "indication"). The term "labeling" under the food and drug laws is given very broad meaning and includes all forms of communication and information disseminated by a manufacturer.

50. Off-label promotion renders a drug or device "misbranded," and violates the FDCA. 21 U.S.C. § 331, 352. The FDCA prohibits the "introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a). Further, it prohibits "the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act . . . results in such article being adulterated or misbranded." 21 U.S.C. § 331(k).

51. Once a drug or device is approved for a particular use, the FDA does not prohibit doctors from *using* that product for purposes different than those approved by the FDA – the manufacturer, however, is prohibited from *promoting* any unapproved use.

52. The prohibition against off-label promotion protects patients and consumers by seeking to ensure that manufacturers do not promote their devices for uses other than those found to be safe and effective by an independent, scientific governmental body – the FDA.

V. The Role of Drugs and Medical Devices in the Treatment of Diabetes.

A. Diabetes: Type 1 Versus Type 2.

53. Diabetes is a condition in which the body is not able to regulate levels of glucose (sugar) in the blood, resulting in too much glucose being present in the blood. An estimated 26 million Americans have diabetes.

54. In Type 1 diabetes, traditionally diagnosed in children or young adults, the body does not produce enough insulin, which is a hormone produced by the pancreas that aids in moving glucose from the blood to the cells.

55. Type 1 diabetes is an autoimmune disease. While it is one of the more common chronic illnesses in children, Type 1 diabetes afflicts less than 10% of all diabetes patients; the remaining suffer from Type 2 diabetes, which is an entirely-different illness from type 1.

56. In Type 2 diabetes, insulin that the body produces is inefficient at moving glucose from the blood to the cells. Some glucose is moved out of the bloodstream, but not as effectively as a person with normal insulin efficiency. This results in high blood sugar. Type 2 diabetes is most common in people who are overweight and obese, and in older populations. According to the American Diabetes Association, about 90 to 95% of all diabetes cases are Type 2.

57. Type 2 diabetes was until recently considered an adult disease. However, with obesity rates more than tripling among adolescents since 1990, the incidence of Type 2 diabetes has rapidly increased among young people.

58. All people, with or without diabetes, need insulin for two reasons: (1) a background amount of insulin for normal functions of the body without food, and (2) a burst of insulin “on demand” when food is eaten. People without diabetes can trust that their pancreas will produce the required amount of insulin for them. People with diabetes need to take insulin as similar as possible to the way their pancreas would produce it if it could.

59. A person with a serious case of diabetes, *i.e.*, significant insulin deficiency,

typically needs to take multiple daily injections of insulin. A common regimen involves four daily injections – before breakfast, lunch, and supper, and before bedtime. With multiple daily injections, some of the insulin is being used for background and some is being used for food digestion.

60. An alternative to multiple daily injections ("MDI") is insulin infusion pump therapy. An insulin infusion pump is a small device that delivers insulin continuously to the body. The insulin is delivered according to a program that is adjusted to each insulin pump wearer. A small amount of insulin is given continually (the "basal rate"). This insulin keeps blood glucose in the desired range between meals and overnight. When food is eaten, the user programs the insulin pump to deliver a "bolus dose" of insulin matched to the amount of food that will be consumed.

61. Historically, insulin pump sales have been to Type 1 diabetes patients, which is only a very small segment of the diabetes market. Consistent with Medicare's stringent coverage requirements for the pump, most physicians do not consider insulin-dependent Type 2 diabetics as pump candidates because the standard of care for these patients is MDI therapy.

62. An insulin pump wearer decides how much insulin will be delivered based upon the results of blood glucose monitoring. The standard home method of blood glucose monitoring is a fingerstick test. This is a do-it-yourself test using a blood glucose meter that measures blood sugar at the time of the test. The individual "sticks" a finger to obtain blood for the test.

63. A more recent development is the use of "continuous glucose monitoring" (CGM) devices. These devices use a "sensor" inserted under the skin, which

continually monitors and measures glucose levels in the bloodstream. The sensor connects directly to a small transmitter, which wirelessly sends the glucose data to a small monitoring device, recorder, or insulin pump. The CGM device is used to detect trends and track patterns in glucose levels for the purpose of making both acute and long-term therapy adjustments. In order to produce a sensor or interstitial glucose value, the CGM device must be calibrated with blood glucose values from a blood glucose meter.

64. The primary medical specialists who treat diabetes patients are endocrinologists and internists.

B. Diabetes Products at Issue in this Complaint.

65. Medtronic sells several products for the treatment and management of diabetes. In fiscal year 2012, Medtronic's total worldwide sales for its diabetes products were $1.48 billion, an increase of almost 20% since the filing of this Complaint (in 2011) alone.

66. In addition to its line of devices, Medtronic's sales practices results in a number of other items and services which are also paid for by government healthcare programs, including diabetes educational training and the physician services resulting from the evaluation and management of patients using its devices (as further explained in Sections VI- VII below).

1. Medtronic's Insulin Pumps.

67. The current models of Medtronic's insulin infusion pump are called the Paradigm Revel ("Revel") 523 and 723. The only difference between the Revel 523 and 723 is the size of the insulin reservoir – the Revel 523 holds 176 units of insulin and the

Revel 723 holds 300 units of insulin. The pediatric models are Revel 523k and Revel 723k. The preceding versions of the pump had the model numbers 522 and 722 (and 522k and 722k for pediatric patients). As used herein, Medtronic's "insulin pump" refers to all varieties of insulin infusion pumps sold by Medtronic during the period covered by this Complaint.

68. Medtronic's insulin pump is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes in persons requiring insulin.

69. Medtronic's insulin pump is about the size of a compact cell phone. It is worn outside the body in a pocket, underneath clothing in a pouch, or on a belt like a phone. The insulin is contained in a receptacle called the "insulin reservoir."

70. The insulin pump delivers insulin from the reservoir into the user's body through a tiny, soft tube (thinner than a strand of spaghetti), which is called the "infusion set." At the end of the tube is an even smaller, softer tube called a cannula, which is approximately a half inch in length. The cannula is inserted under the skin by a needle.

71. The current retail price of Medtronic's insulin pump is approximately $6,500. The pump reservoir and infusion sets are disposable devices. They are supposed to be replaced every two to three days. The current retail price of a monthly supply of reservoirs and infusion sets is approximately $200 per month.

2. Insulin Promoted by Medtronic.

72. Medtronic's pump is approved for use with Humulin R U-100 ("U-100") insulin, which means there are 100 units of insulin per milliliter of fluid in the vial. Medtronic represented to the FDA the pumps "are designed to deliver 0.00 to 35.00 units of U100 insulin per hour in basal rates and up to 25.00 units of U100 insulin per

meal or meal bolus." Similarly, other manufacturers' insulin pumps are also only approved by the FDA for use with U-100 insulin.

73. The insulin is not manufactured by Medtronic, and is separately prescribed by the physician.

74. Medtronic exclusively promotes insulin manufactured by Eli Lilly, a pharmaceutical manufacturer with which Medtronic formed a strategic alliance for the purposes of insulin promotion. In fact, Eli Lilly does not separately promote its U-500 insulin products.

75. As alleged further below, Medtronic improperly promotes a U-500 insulin manufactured by Eli Lilly to be used with its pump, notwithstanding that neither the U-500 insulin nor its pump is approved for that use. Rather, U-500 insulin, an insulin with five times the concentration as U-100, is approved only for use as an injection.

3. Medtronic's Continuous Glucose Monitoring Devices.

76. Medtronic's Guardian REAL-Time System (the "Guardian") is a continuous glucose monitoring ("CGM") device sold both as a stand alone product and combined with an insulin pump in an integrated system. The integrated system is called the Paradigm REAL-Time System and is discussed below.

77. The Guardian CGM device is approved for continuous or periodic monitoring of glucose levels in the fluid under the skin in persons with Type 1 or Type 2 diabetes. It is approved as an adjunctive device to complement, not replace, information obtained from standard home glucose monitoring devices.

78. The Guardian CGM device consists of a (i) glucose sensor (ii) a transmitter, and (iii) a small monitor. The sensor is connected to the transmitter, which

sends glucose readings every five minutes to the monitor. The sensor is inserted under the patient's skin by an insertion device that uses a large needle.

79. The most expensive component of the CGM device is the glucose sensor, which currently costs approximately $42 retail.

80. The FDA has approved Medtronic's glucose sensor for a maximum of three days of use. A monthly supply of 10 sensors costs approximately $420.

4. Medtronic's iPro Professional CGM Device.

81. Medtronic offers physicians a professional CGM product, called the iPro CGM ("iPro"). The iPro is similar to the personal CGM device except that the iPro does not have a monitor and the display of data is retrospective instead of real time. The device stores the data in a recorder, which is later downloaded in the physician's office.

82. The patient is fitted with the iPro device in the physician's office and sent home wearing the device to collect glucose data over several days. After the data is downloaded onto a computer, it can be interpreted to make treatment recommendations based on the glucose patterns revealed by the data.

5. Medtronic's Integrated Diabetes Management Device.

83. Medtronic's "MiniMed Paradigm REAL-Time System" (hereafter, "Paradigm RT") combines Medtronic's insulin pump with Medtronic's glucose sensor into an integrated system. The sensor communicates with the pump, and data from the sensor can be downloaded through software called "Carelink," which allows the data to be viewed in a computer for patient or physician use. The pump provides an alert if the sensor detects that glucose levels fall below or rise above preset values. The pump monitor provides a trend graph to show current glucose trends.

VI. Government HealthCare Programs.

84. An estimated 26 million Americans have diabetes, and at least half of those are government healthcare program beneficiaries. This is an alarmingly growing market: In 2004, for example, the Center for Medicare and Medicaid Services ("CMS") estimated that more than 20%, or 6.3 million, of the 31.3 million Medicare beneficiaries in the United States had diabetes.[1] By 2010, Medicare beneficiaries with diabetes more than doubled that number, rising to 13 million.[2] At that rate, by 2020, it is estimated those numbers will rise to 21 million.[3]

85. The Medicare program is administered by CMS on behalf of the Secretary of HHS (the "Secretary"). CMS contracts with so-called "fiscal intermediaries," typically private insurance companies, to act as agents of the Secretary in administering the Medicare program. In conformity with federal law, these intermediaries review claims to determine whether they are appropriate for reimbursement.

86. Medicare "Part A," 42 U.S.C. §§ 1395*c*-1395*i*, provides insurance for covered inpatient hospital and related services. Medicare "Part B," 42 U.S.C. §§ 1395*j*-1395*w*, is a supplemental program insuring other items and services, such as out-patient hospital and physician services, supplies, and laboratory tests. Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

87. Medicare Part B is the part of the program that covers most of the items

[1] Adler, Gerald S. Centers for Medicare and Medicaid Services, Diabetes in the Medicare Aged Population, 2004, *available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/07-08Winterpg91.pdf

[2] Working Paper 5 at p.10-11, The United States of Diabetes: Challenges and Opportunities In the Decade Ahead (November 2010), *available at* http://www.unitedhealthgroup.com/hrm/UNH_WorkingPaper5.pdf.

[3] *Id.*

and services described herein. When provided in accordance with Medicare conditions of payment, Medicare Part B generally covers, for example, external insulin pumps for a limited set of eligible beneficiaries, the prescription for insulin when used in conjunction with the pump, home blood glucose monitors, professional continuous glucose monitoring ("GCM"), diabetic self-management training (DSMT) services, and the professional services which may be rendered by physicians in the treatment of diabetes (including evaluation and management ("E&M") services provided in conjunction with professional GCM). *E.g.,* Local Coverage Summary, United Healthcare Medicare Advantage Plans, Diabetes Management, Equipment and Supplies.

88. Medicare Part B generally pays for the drugs and devices at issue at 80% of the allowable charge. For physician services, Medicare uses reimbursement rates calculated and published annually by CMS, based on location of the provider, using Current Procedural Terminology ("CPT") codes.[4]

89. Medicaid is a public assistance program providing for payment of medical expenses for the poor and disabled. Funding for Medicaid is shared between the federal government and state governments. For dual-eligible patients (those eligible for both Medicaid and Medicare), Medicaid pays the deductible for Medicare patients.

90. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding, which

[4] CPT codes seek to assign standard levels of reimbursement to standard medical procedures based on the effort and expense normally associated with efficient administration of such care. CPT code reimbursement includes a professional services component designed to compensate for services rendered by doctors or other qualified medical professionals (such as licensed nurse practitioners or physician assistants) and/or a technical component payment that is intended to reimburse costs associated with equipment and supplies needed to perform outpatient diagnostic or treatment procedures.

is called federal financial participation. 42 U.S.C. §§ 1396, et seq. Under these minimum requirements, Medicaid also provides coverage for use of medical devices. 42 C.F.R. § 440.70.

91. In addition to Medicare and Medicaid, the federal government provides reimbursement, in whole or part, for approved drugs and medical devices under several other federal health care programs, including, but not limited to, CHAMPUS/TRICARE, CHAMPVA, the Federal Employees Health Benefit Program, and the Indian Health Service.

92. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disabilities. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors. The Indian Health Service, administered by the Department of Health and Human Services, provides health services to Native Americans.

93. In addition to the federal programs, the States provide a number of state-funded healthcare programs.

VII. Material Conditions of Payment of Government Healthcare Claims.

94. Government healthcare programs establish the terms and conditions under which providers and suppliers may submit claims to government healthcare programs.

95. Every provider and supplier agrees to comply with those terms and conditions in order to be eligible to provide services or supplies to government healthcare program beneficiaries.

96. Compliance with applicable healthcare statutes and regulations is a condition of payment of all government healthcare claims. In turn, the failure of comply with governing healthcare statutes and regulations would have a natural tendency to influence the Government's decision to pay those claims.

97. Medical devices and associated items and services for the treatment of diabetes are only eligible for reimbursement by government healthcare programs if they satisfy the conditions of payment relevant to those items and services.

A. Compliance with the AKS and Stark Statute Are a Material Condition of Payment of Government Healthcare Claims.

98. As articulated in Sections II – III above, compliance with the AKS and Stark Statute are a material condition of payment for all claims paid in whole or in part by government healthcare programs.

B. Compliance with Coverage Requirements Are a Material Condition of Government Healthcare Claims.

99. Medicare's coverage requirements are also a material condition of payment of claims for Medicare beneficiaries. Medicare pays for certain items and services associated with the treatment of diabetic patients, subject to specific pre-conditions for coverage.

100. For example, Medicare only covers the use of an insulin pump for certain beneficiaries, namely individuals with Type 1 diabetes and those with Type 2 diabetes who have, over time, lost the ability to make insulin (such that their laboratory results

demonstrate that their insulin resistance mimics that of a Type 1 patient). Moreover, Medicare recognizes that the use of the pump is only effective for those patients who have demonstrated effective self- management (such as regular blood glucose testing).

101. Thus, Medicare will only cover pumps for diabetic beneficiaries who have a documented fasting C-peptide (connecting peptide) level "that is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method" and a concomitant fasting blood sugar less than or equal to 225 mg/dl (C-Peptides are created by the breakdown of the initial forms of insulin in the body so C-peptide levels serve as a measure of the amount of insulin that the body makes). Medicare Coverage Issues Manual, § 60-14 (September 2001); *see also* National Coverage Determination § 280.14 (February 18, 2005).

102. In addition, Medicare requires the following specific conditions to be met before it will pay for an insulin infusion pump:

> In order to be covered, patients must meet criterion A or B:
>
> (A) The patient has completed a comprehensive diabetes education program, and has been on a program of multiple daily injections of insulin (i.e. at least 3 injections per day), with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, **and** meets one or more of the following criteria while on the multiple daily injection regimen:
>
> (1) Glycosylated hemoglobin level (HbAlc) > 7.0 percent
> (2) History of recurring hypoglycemia
> (3) Wide fluctuations in blood glucose before mealtime
> (4) Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl
> (5) History of severe glycemic excursions
>
> (B) The patient with diabetes has been on a pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an

> average of at least 4 times per day during the month prior to Medicare enrollment.

Id. at § 60-14 (emphasis added).

103. Once these conditions are met, the pump must be ordered by (and the patient's follow-up care must be managed by) a physician who manages multiple patients with insulin pumps and "who works closely with a team including nurses, diabetes educators, and dietitians who are knowledgeable in the use of [pump therapy]." *Id.* at § 60-14.

104. Other government insurance programs follow similar pre-conditions for payment of insulin pump therapy. *See* Providing Diabetes Health Coverage: State Laws and Programs, National Conference of State Legislatures (May 2011) (compiling program requirements).

105. Medicare Part B also pays for the drug (the insulin) used with the pump subject to certain preconditions. A prescription drug used in conjunction with DME must be furnished directly to the patient by the entity dispensing the drug pursuant to a written prescription. MBPM, Ch. 110.3. Moreover, "a supplier that is not the entity that dispenses the drugs cannot purchase the drugs used in conjunction with DME for resale to the beneficiary." *Id.*

106. Medicare Part B also covers diabetes self-management training services ("DSMT"). As a material condition of payment of those services, "the treating physician or treating qualified non-physician practitioner who is managing the beneficiary's diabetic condition must certify that such services are needed." MBPM § 300 (July 21, 2007). Medicare Part B covers 10 hours of initial training for a beneficiary who has been diagnosed with diabetes, and follow-up training each subsequent calendar year. MBPM

§ 300.1.

107. DSMT must be provided by an accredited DSMT program and billed by a certified provider, who has entered into a supplier agreement to bill federal programs. *Id.* at § 300.2. The "incident to" requirements of section 1861(s)(2)(A) of the Social Security Act do not apply to DSMT services. MBPM § 300.4.1.

108. DSMT services are billed under HCPCS codes G0108 or G0109. Reimbursement rates are re-calculated annually. By way of example, these codes were reimbursed approximately $54.70 (increased from $23.45) and $18.69 (increased from $12.99) per 30 minutes in FY 2011.

109. Continuous Glucose Monitoring Systems (CGMS) are generally not covered by government programs for daily personal use, but are covered one-time or occasional testing as a Part B physician reimbursement, for intervals of not less than 24-hours, and as generally recommended for periods of 72 hours as medically necessary. Physicians can bill the start, removal, download, and/or any technical training required for the CGMS under CPT code 95250 and can bill the data interpretation associated with CGMS under CPT Code 95251. Physicians may also bill for pre- and post-office visits associated with CGMS, as "Evaluation & Management" ("E&M") services under CPT Codes 99212-99215.

110. Replacement of the insulin pump may only be made, at a patient's election, "if the reasonable lifetime of such an item, as so established, has been reached during a continuous period of medical need, or the carrier determines that the item is lost or irreparably damaged it is reasonable and necessary." 42 U.S.C. § 1395(m)(a)(7)(C). The "reasonable useful lifetime" of DME is 5 years. *Id.*

111. As a material condition, the statute governing Part B payment specifies, however, that replacement must be at the patient's election and cannot be solicited by the medical device supplier, unless:

> (i) The individual has given written permission to the supplier to make contact by telephone regarding the furnishing of a covered item.
>
> (ii) The supplier has furnished a covered item to the individual and the supplier is contacting the individual only regarding the furnishing of such covered item.
>
> (iii) If the contact is regarding the furnishing of a covered item other than a covered item already furnished to the individual, the supplier has furnished at least 1 covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

42 U.S.C. § 1395(m)(a)(17)(A).

112. The statute further provides that if a supplier contacts an individual in violation of the statutory prohibitions, "no payment may be made … for any item subsequently furnished to the individual by the supplier." Id. at 1395(m)(a)(17)(B).

113. Moreover, an upgraded insulin pump can only be made if it is reasonable or necessary. A medical device is not reasonable and necessary if it "exceeds the patient's medical need." Medicare Program Integrity Manual, § 13.5.1.

C. Drugs and Devices Must Be Supported By A Demonstration of Safety and Effectiveness as a Material Condition of HealthCare Claims.

114. As a material condition of payment, Medicare requires that all items and services be "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 C.F.R. § 411.15(k)(l).

115. A item or service is "reasonable and necessary" for purposes of Medicare coverage if it is:

- *Safe and effective* and

- *Appropriate*, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:

    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
    - Furnished in a setting appropriate to the patient's medical needs and condition;
    - Ordered and furnished by qualified personnel;
    - One that meets, but does not exceed, the patient's medical need; and
    - At least as beneficial as an existing and available medically appropriate alternative.

Medicare Program Integrity Manual, § 13.5.1 (January 15, 2013) (emphasis added).

116. Even when used with DME, the prescription for insulin must be accompanied by a determination that the drug or biological itself is reasonable and necessary for the patient's treatment. Medicare Benefit Policy Manual ("MBPM"), Ch. 110.3; MCM § 60-14.

117. However, drugs or biologicals are only considered safe and effective when approved for marketing by the [FDA] and used for indications specified on the labeling. MBPM at Ch. 50.4.[5]

118. Unlabeled uses of a drug are presumptively not safe and effective, and could only be covered in the circumstance that "the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice." *Id.* at 50.4.2.

119. Medicaid also only covers outpatient drugs dispensed by prescription and approved as safe and effective under the FDCA, 21 U.S.C. §§ 355 & 357, and does not

[5] A prescription drug is not considered a "drug or biological" under Medicare if it is not included, or approved for inclusion, in the latest official edition of the United States Pharmacopoeia National Formulary (USP-NF), the United States Pharmacopoeia-Drug Information (USD-DI), or the American Dental Association (AOA) Guide to Dental Therapeutics, which contain medically accepted uses for generic and brand name drug products." MBPM, Ch. 50.1

include “a drug or biological used for a medical indication which is not a medically accepted indication.” 42 U.S.C. § 1396r-8(k)(2),(3). A “medically accepted indication” includes any use for a covered outpatient drug which is approved under the [FDCA], or the use of which is supported by one of the three compendia recognized by the Medicaid statute - the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (and its successor publications), and the Drugdex Information System. *Id*. at § 1396r-8(g)(1)(B)(i).

120. Other government healthcare programs also follow suit, and restrict coverage to labeled uses. *E.g.*, 32 C.F.R. Part 199; TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B)(2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

121. “Medical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not reasonable and necessary…. Program payment, therefore, may not be made for medical procedures or services performed using devices which have not been approved for marketing by FDA.” Medicare Intermediaries’ Manual § 3151.1.

122. Under the MDA, medical devices are classified according to the stringency of regulatory control necessary to ensure safety and effectiveness. 21 U.S.C. § 360c(a). Certain devices, such as those at issue in this case, require FDA "premarket approval" before they may be commercially distributed to the general public. Such devices are considered "Class III" devices, defined by the Medicare regulations as those for which “there is insufficient information to determine that either special or general controls would provide reasonable assurance of safety and effectiveness.” 42 C.F.R. §

405.201(b). Premarket approval is required so that the manufacturer furnishes detailed information about the device's testing, design, components, performance standards, manufacturing, packaging, and labeling" sufficient to reasonably assure the FDA that the device is safe and effective. 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20 (1994)); 21 U.S.C. § 360c (a)(1)(C).

123. The safety and effectiveness determination is specifically premised on factors which include the condition of the device's intended beneficiaries and the circumstances of the device's use. 21 C.F.R. 860.7(b).

124. Off-label uses of a device are not within the scope of the devices pre-market approval, and are not deemed safe and effective. Without a demonstration of its safety and effectiveness, such devices do not meet the definition of what is “reasonable and necessary” for the purposes of Medicare coverage. Medicare Program Integrity Manual, § 13.5.1

125. Other government healthcare programs follow suit. TriCare, for example, defines it in this way: Coverage for off-label uses of a device may only be considered when

> the off-label use is medically necessary and demonstrations from medical literature, national organizations, or technology assessment bodies show that the off-label use of the device is safe, effective and in accordance with nationally accepted standards of practice in the medical community. If the device is FDA approved and the off-label use is medically necessary, supported by medical literature identified by the contractor, which indicates the device is nationally accepted as standard practice, and is not otherwise excluded, the contractor may approve the cost-sharing for the off-label medical device.

TriCare Policy Manual, Ch.8 § 5.1. at 2.3.2 (2012).

126. The off-label uses of the drugs and devices described herein are not supported by demonstrations that the unlabeled use of the drug and device is safe and

effective and in accordance with nationally accepted standards of practice.

FACTUAL ALLEGATIONS

I. Medtronic's Corporate Structure and Strategy.

A. Medtronic's National Sales Strategy.

127. Sales and marketing of Medtronic's diabetes products in the United States are handled by Medtronic's Diabetes Operating Segment, also known as the Diabetes Division.

128. Sales of insulin pumps and pump accessories are the largest source of revenue for Medtronic's Diabetes Division, which had $1.48 billion in revenue in FY 2012.

129. Insulin pump therapy is a relatively recent addition to the treatment for diabetes, and has been generally considered only appropriate for patients with Type 1 diabetes.

130. However, only a small fraction of the total population are Type 1 diabetics. Rather, approximately 90 to 95% of all diabetes patients are Type 2 diabetics, and the sheer number of those beneficiaries are rising. While Type 1 diabetics do not naturally produce insulin, Type 2 diabetics are those whose bodies have become resistant to insulin over time. Type 2 diabetics are often overweight, disabled, or have other chronic conditions and comorbidities.

131. In 2010, Medicare beneficiaries with diabetes rose to 13 million, nearly doubling their numbers since 2004, and representing more than half of the American diabetes population.

132. The standard of care for the treatment of the vast majority of these

diabetic patients (generally with Type 2 diabetes) has been the self-administration of multiple daily injections of insulin ("MDI" therapy). Decision Memo for Insulin Pump: C-Peptide Levels as a Criterion for Use (CAG-00092R) (December 17, 2004) quoting 2003 National Institute for Clinical Excellence (NICE) technology appraisal on "Guidance on the Use of Continuous Insulin Infusion for Diabetes."

133. As recognized by CMS, NICE concluded that the use of the insulin pump is not recommended for patients with Type 2 requiring insulin therapy. *Id.* Insulin infusion pumps are considered experimental and investigational for all persons with Type 2 diabetes. Decision Memo, *citing* Aetna Clinical Policy Bulletin #0161.

134. In recognition of this, Medicare concluded that the "use of the [insulin pump] is rarely indicated in [Type 2 patients] and that strict criteria should be used for eligibility." *Id.* Thus, Medicare only covers insulin pump therapy for Type 2 diabetics if their condition is so severe that that their laboratory tests satisfy Medicare pre-conditions for insulin-resistance (in essence, mimicking a Type 1 diabetic).

135. In order to continue to increase sales, Medtronic recognized that it needed to "expand indications" for the use of its pumps. Medtronic records indicate that approximately 35% of Type 1 diabetes patients are already on an insulin pump, and that sales in this market had become generally flat.

136. As a result, Medtronic advanced a national sales strategy to increase the new patients to pump therapy ("NPT") – primarily Type 2 and newly diagnosed pediatric patients -- by creating a package of incentives for providers treating diabetes patients.

137. These incentives included illegal remuneration, as well as false representations to physicians regarding the reasonableness and necessity of pump use

for all its patients.

138. Thus, many of Medtronic's illegal practices alleged in this complaint target Medicare patients on MDI therapy. These patients are prime targets for insulin pump sales because going on a pump saves them money. This is because Medicare Part B pays for the pump *as well as the insulin that goes into the pump*; whereas MDI patients not on a pump must purchase insulin under their prescription drug plan (Medicare Part D). Selling these patients an insulin pump shifts the cost of their diabetes care to Medicare.

B. Medtronic Incentivizes Its Sales Force to Implement This Directive.

139. Within the Diabetes Division, sales and marketing efforts are undertaken through five geographic Regions, each of which is divided into Districts, which are further divided into Sales Territories.

140. The sales representatives within each Territory are called Territory Manager or Senior Territory Manager, depending on seniority level and merit promotion. (Both positions will hereafter be referred to as "Territory Manager" or "diabetes sales representative.") Within the Diabetes Division, there are approximately 185 Territory Managers nationwide. Territory Managers are assisted by Diabetes Clinical Managers ("DCM") – who are Registered Nurses or Registered Dieticians – and by Diabetes Therapy Assistants ("DTA"), who are insurance specialists. Medtronic also employs a number of Diabetes Therapy Consultants ("DTC"), who generally have a college degree but no clinical training, who make telephone solicitation calls for Medtronic. In addition, Medtronic has approximately 25 Associates and/or Associate Managers nationwide. Their job is to overlap territories with high volume and to work mainly with primary care

offices.

141. The Territory Managers report to a District Sales Manager, who reports to the Regional Sales Director, who reports to the Vice President of Diabetes Sales.

142. While employed by Medtronic, Relator was one of approximately seven Territory Managers within the Oregon South Territory, which is in the Pacific Northwest District, within the Western Region.

143. Relator's immediate boss when Relator was terminated was Mike Ware, District Sales Manager for the Pacific Northwest. Mike Ware replaced Travis Allen in that position in July 2010. Prior to Travis Allen, Douglas Villiers held the District Sales Manager position. Before Mr. Villiers, David Merrick held that position. Mr. Merrick was Relator's hiring manager.

144. Mr. Ware reports to Mike DiGiulio, Regional Sales Director for the Western Region. The Regional Sales Director for the Northeast Region, which includes this judicial district, is Bob Higley. Mr. DiGiulio and Mr. Higley report to Mike Gill, Vice President of Sales for the Diabetes Division. Mr. Gill's counterpart on the Marketing side is Greg Meeham. The Vice Presidents report to Katie Szyman, President of the Diabetes Division.

145. Strategic decision-making concerning the sale and marketing of Medtronic's diabetes products in the United States is centralized in Medtronic MiniMed's headquarters in Northridge, California (although some functions are also being performed at other offices). That office dictates diabetes sales and marketing strategy for all of the sales Territories throughout the nation.

146. Medtronic sales representatives receive incentive-based compensation

that includes an annual salary, plus a commission. The commission is determined by the sales representative's performance in the relevant market and whether s/he satisfies or surpasses sales targets.

147. Moreover, Medtronic sets aggressive and constantly increasing sales quotas for its sales force, including the number of new patients to the pump (NPT) per month. Failure to meet sales quotas can result in termination. The turnover among Medtronic sales representatives is one of the highest in the industry.

148. Sales representatives who exceed their quota stand to make huge commissions and bonuses, adding up to hundreds of thousands of dollars. For example, the sales commission for every new insulin pump sale that exceeds quota is 20%, which translates into $1,000 per sale if the pump sells at a modest contract rate of $5,000. The commission for insulin pump upgrades is 10%.

149. Medtronic expects and directs its sales force to successfully execute the schemes alleged herein.

150. Medtronic expects results from these schemes in order to maintain continued employment, including increasing pump orders from government healthcare programs.

II. Medtronic Caused the Submission of False Claims in Violation of the AKS and Stark Statute.

151. As further described below, Medtronic employs a variety of methods to offer and pay remuneration to physicians and other healthcare providers to induce them to refer, recommend, or arrange for the purchase of Medtronic's diabetes products, in violation of the AKS and Stark Statute.

152. Remuneration, for purposes of the AKS and Stark, includes anything of

value offered to referral sources, whether in cash or in kind, or offered directly or indirectly.

153. Medtronic offered many different types of remuneration to those in a position to influence referrals, including to physicians, physician practitioners and nurses, physician practices and treatment centers. The range of remuneration offered included:

- Free clinical and billing support for the physician's use of professional CGM, including the use of the sales representative to execute clinical functions;
- Opportunities for increased billing with increased Medtronic referrals;
- Cash payments for training;
- Free services in the form of a nurse acting as diabetes clinical manager for the practice or center;
- Free supplies; and
- Free lunches, dinners, or "VIP" trips.

154. The remuneration offered was above fair market value, and offered for the purpose of obtaining orders from the provider for Medtronic products.

155. In order to induce the providers to use Medtronic, remuneration was offered as part of an Economic Presentation to the provider, with the expectation that the provider could accept all or part of it, as long as it resulted in increased sales to Medtronic.

A. Remuneration Offered and Paid by Medtronic To Induce Referrals.

1. The Economic Package.

156. Medtronic sales representatives were instructed to present an "Economic Model" to healthcare providers, which would demonstrate the economic value offered by

Medtronic, and the revenues that would result from increasing orders of Medtronic products.

157. These instructions are illustrated in a PowerPoint entitled "Economic Model/Reimbursement –The Economic Stimulus Package for your Health Care Providers," authored by the Senior Territory Manager in the Sacramento East Territory. In this PowerPoint, sales representatives are instructed to "Assess[ ] the Account" because the "[t]he ultimate decision maker is not always the physician- don't assume." In that assessment, the sales representative must get to know the economics of the office and understand "who has a stake in the profitability or liability of the practice."

158. Indeed, one of the first things a sales representative must do with a new provider target is to fill out an "Account Profile Form" tracking, among other things, the number of Type 1 and Type 2 insulin taking patients, and the Medicare mix of the practice.

159. Once the sales representative understands the needs of the office, he or she can offer a range of "Economic Reimbursement Tools" including, as the "Economic Stimulus Package" PowerPoint bullets out:

- Economic Model
  5+5=10 [demonstrating the billing resulting from ordering Medtronic products]
- Connect the Dot Program [a program that included paid trips and symposiums]
- iPro Clinics/reports
- Advance [referring to a resource offered to providers, including presentations about how to obtain reimbursement for Professional CGM]

- EOB's=Checks [demonstration of revenues using actual billing obtained from other providers]
- CGM Continuum [referring to providing sales representatives to support CGM and turn patient opportunities into pump sales]
- Center Contracts [paid training contracts]
- Webinar [including webinars on product training and billing and coding]
- Directly sell against Dexcom and Navigator [competitor products].

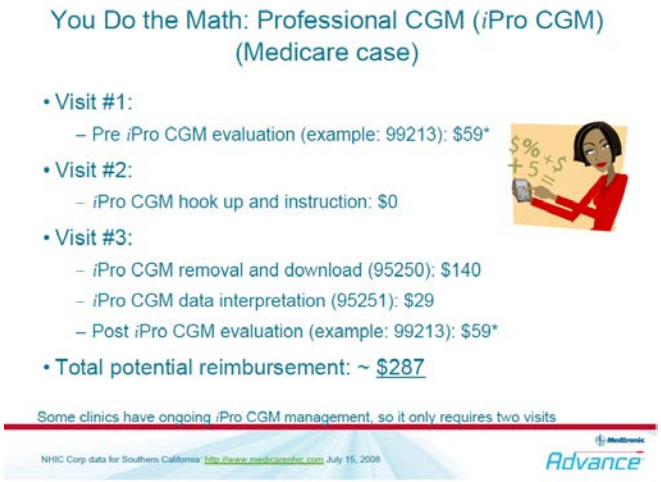
160. The "Economic Model" is the primary tool used by sales representatives to demonstrate the dollar value of its incentives to providers. This tool was an interactive computer program, that sales representatives has available on a computer or iPad. The program allowed the representative to fill in variables about the provider's practice, including the area of the country of the practice (because billing rates vary by region), the number of insulin-producing patients seen per week, the percentage of patients on Medicare (because Medicare reimburses at a different rate than private insurance), and the start-up costs that may be involved (such as purchase of the professional GCM device). When these and other variables are plugged in, the Economic Model shows the billing opportunities for the provider for both the use of professional GCM ("iPro") on diabetic patients and the additional billing opportunities available if a pump is ordered for each iPro patient.

161. Indeed, in more recent iterations of that Tool, the program allows the sales representative to show a provider his or her "Practice Potential" by doing added procedures. After entering the information, the Reimbursement Tool shows the provider three "Options" demonstrating that adding "additional procedures" generates additional net reimbursement. Each Option shows the incremental revenues with additional

Orders, and the provider is then asked to choose an "Option" so that he can start ordering Medtronic products and generating revenue.

162. The billing opportunities are potentially ample. If a provider orders iPro for a patient, the provider is able to bill for the startup, removal, download and technical training related to the device under CPT Code 95250, and then interpretation of the data from the professional GCM under CPT code 95251. Then, physicians can also bill for office visits before and after the iPro clinics as "Evaluation & Management" ("E&M") under CPT Codes 99212-99215.

163. In Medtronic's words, "You do the Math:"



164. If the iPro opportunity was turned into an order for a pump, there were additionally billing opportunities. In that case, the provider could bill for one pre-visit and three post-visits under E&M codes, as well as for educational training (DSMT) for the patient, if the practice was a certified DSMT provider. As identified in a 2009 PowerPoint entitled "iProTM Reimbursement & Impact to Your Territory Practices," – "Tips from the Top" (authored by a Corporate Account Manager), the conversion of an iPro patient to the pump could result in more than a "~$500 reimbursement opp. per pt."

for the healthcare provider.[6]

165. The driving force behind this Economic Model is Medtronic's strategy to leverage the use of iPro's by providers into opportunities to drive pump sales, called the "CGM Continuum." Under this strategy, sales representatives were to convince providers, through incentives and otherwise, to set up patients who are on conventional therapy (such as MDI (injections) and orals) on an iPro, and then transform those patient opportunities into new orders for pump therapy. The sales representatives were directed to establish themselves as part of the "infrastructure" of a provider's practice or center, and run "clinics" at the provider's location in order to provide free assistance to practice and have direct access to patients to further influence the request for pump therapy.

166. As an "iPro clinic," the provider had access to an array of benefits, in addition to increased billing. Medtronic provided its own sales representatives as a "consultant" to the office to assist with the execution of the start, removal and download of data for which the physician was billing a professional service. Medtronic routinely offered loaner equipment to reduce the physicians' start-up costs. Medtronic also offered the services of a Medtronic-paid nurse to act as a clinical manager, and offered to pay personnel at the provider's office to provide the pump training. Medtronic also offered other incentives, such as lunches, dinners, and paid trips to the corporate offices to meet Medtronic executives and learn about Medtronic's products.

167. This "Economic Stimulus" package was offered to Medtronic's targets, and

[6] Medtronic also taught the provider how to bill these codes so they could maximize reimbursement. Medtronic also instructed the provider to bill the E&M code and the GCM code with a modifier to indicate that the services were provided in one day.

a range of combinations of these incentives were successfully implemented at providers around the country in exchange for orders of Medtronic products.

2. iPro and iPro Clinics.

168. Medtronic's strategy was to find ways to expand into new markets for its pump. As previously discussed, pumps had been traditionally relegated to Type 1 patients, an audience which had flattened out. The growing market is with patients with Type 2 diabetes, a population comprised of significant percentages of government healthcare beneficiaries. And, Medtronic well knew that it needed government payor patients, as the only viable purchasers of an insulin pump (with a retail price of $6,500) are patients that are eligible for insurance reimbursement for the device.

169. Thus, the primary target for transforming iPro use into new pump orders were Type 2 patients who were not previously on the pump. As explained at the 2008 National Sales Meeting, in a presentation entitled "Professional CGM Clinics," the road to a successful CGM clinic was to "[f]ocus on the goal → NPNP" (referring to new patients to new pump). In a breakout at the 2009 sales meeting, a PowerPoint directs "Key Takeaways: Make sure you set the precedence early so you aren't getting pumpers coming to your iPro clinic" and "Expanding Indications."

170. Medtronic rolled out iPro clinics as its national sales strategy, with strict directories to its sales team regarding how it would be implemented. In 2008, shortly after the FDA approved Medtronic's iPro CGM device for sale to physicians, Vice President of Sales, Mike Gill, made iPro clinics the top priority and "deliverable" (*i.e.*, mandatory action) for the sales force. Initially, the deliverable for the sales force was to conduct four iPro clinics with four MDI patients every month. In fiscal year 2011, this

requirement was increased to five iPro clinics with four MDI patients every month.

171. The term “iPro clinic” refers to a session in a doctor’s office in which several diabetes patients are invited to be fitted with the Medtronic iPro CGM device for the ostensible purpose of evaluating their current diabetes management and making improvements.

172. However, the true purpose of the iPro clinic was a *quid pro quo*: Medtronic provides physician’s offices with free services, including the services of Medtronic employees to run the iPro clinics, knowing that the doctors will bill government healthcare programs for these services; in exchange, providers cooperate with the sales representatives to transform iPro visits into pump sales.

173. An iPro clinic involves several diabetes patients coming into the doctor’s office on the same day to be fitted with Medtronic’s iPro CGM device. On this initial visit, the glucose sensor of the CGM device is inserted under the skin of each patient using a needle, and the sensor is hooked up to a recorder. The patients are given various instructions and sent home for several days while the device continuously records their glucose levels. The patients are scheduled to return to the office several days later to have the device removed and the recorded data downloaded to a computer in the physician’s office for evaluation and interpretation.

174. Medtronic viewed the iPro clinics as an opportunity to gain access to MDI patients in order sell them on Medtronic’s insulin pump. Both the initial visit to set up the CGM device and the second visit to remove the device and download the data offer the opportunity to talk with the patients and sell them on the advantages of insulin pump therapy in place of their current MDI regimen.

175. This goal was continually emphasized: For example, presentations to the sales force at other sales meetings reiterated that the goal of the iPro clinic is to "Gain Access to Patients" and "Execute on iPro Clinics & we will exceed our NPT goals." The sales team was routinely directed to use "CGM is a revenue opportunity for HCPs [Health care practitioners] … Make Sure Your HCPs Know This!" and to "Reinforce [the economic benefit of iPro clinics] with local EOBs to gain economic buy in" and "Be on scene to harvest Opps." (An "Opp" was an opportunity for a pump order, and Medtronic sales representatives were trained to pre-fill and submit a pump order for every patient opportunity.)

176. As part of its strategy, Medtronic used its "iPro Clinic" arrangement to gain one-on-one access to MDI patients.

177. In a one-on-one situation, Medtronic sales representatives can "interpret" the results of the continuous glucose monitoring as evidence that the patient needs an insulin pump, whether or not the patient truly needs a pump. Continuous glucose monitoring inevitably shows fluctuations in the glucose levels of the patient and "excursions," *i.e.*, readings above and below safe glucose levels. Medtronic sales representatives are trained to "interpret" CGM data in a manner to raise fears in the patients' minds and show the provider the purported need for pump therapy.

178. Moreover, the use of the Medtronic sales representatives for the patient visits allows Medtronic to sell its Economic Model to providers. By running the clinics, Medtronic frees up time for the provider and/or the provider's staff, notwithstanding that the provider is billing government healthcare programs for these services.

179. As illustrated in Medtronic training material, "iPro Step by Step,"

Medtronic directs its sales representatives to perform a range of services that provide value to the provider, including:

> Perform Courtesy Sensings:
> •...at the MD's office
> • Talk to patient about CSII
> • Get insurance information, signed AOB
> • Call patient next day
> • Fax LMN
> • Retrieve, Download, Review tracings with MD
> • MD and patient should expect to talk about the PRT at next appointment

180. As part of its selling of the "CGM continuum," sales representatives are instructed to "Clarify the available Medtronic Support" combined with the "attractive reimbursement" available to the provider. Medtronic representatives are trained to identify the "WIFFM" (What's in it for me) for the physician.

181. Indeed, in an August 10, 2009 email on "ROI," a sales representative showed that, at Mary Bridge Children's Hospital, Medtronic was able to assist the staff "to generate enough RVU's [the relative value unit used to calculate physician compensation] to add another FTE" (full-time employee). Thus, "[h]aving tools like iPro allow us to be true consultants to the office/clinic."

182. Finally, Medtronic knew that if it could position its sales representatives to be alone in the room with an MDI patient during the iPro clinic, it could increase its chances of making a pump sale, particularly if the patient is on Medicare. Because a Medicare patient on MDI has to pay for the insulin out of pocket or through his or her Medicare Part D prescription drug plan, while Medicare Part B covers the cost of the insulin pump, the pump accessories, and the insulin (subject to patient co-pay), Medicare patients can be persuaded by the sales representatives to request a pump order from their treating physician.

183. Indeed, the sales representative is expected to automatically begin the pump order process for every interested patient, and pre-fill the order for the physician.

184. Medtronic influences the patients, as well as the providers, with as many incentives as possible. Medtronic also offers patients free supplies and waivers of co-pays, in order to induce them to request the pump. Medtronic also falsely represents to patients and providers that the use of the glucose sensor component of the iPro can be stretched to seven (7) days. Medtronic's sensor has been approved for a three day maximum length of use approved by the FDA, and there is a lack of safety and efficacy evidence to using it for longer periods. However, Medicare patients have to pay for that component out of pocket, so Medtronic regularly promotes longer off-label use of its sensors to incentivize patients to agree to pump therapy.[7]

185. In internal communications, Medtronic managers are very candid about the necessity of sales representatives to insert themselves into the middle of the iPro clinics in order to create an "Opp," i.e., a sales opportunity to sell an insulin pump to the patient. Medtronic managers knew that without Medtronic's involvement, the physicians will simply use the information gained from the continuous glucose monitoring device to adjust the patient's current MDI regimen.

186. For example, a January 2, 2009 email from Travis Allen, then District Manager for the Pacific Northwest, to the sales force in his District, stated:

> Put yourself in each of these [iPro] clinics at each start if possible. Ensure they do their starts on established days so you can be there. If they do

[7] Medtronic induces this off-label use of the sensor by misrepresenting to patients that it is safe and effective, and misrepresenting that it expects approval from the FDA for an expanded indication to 6 days. These representations harm patients. Medtronic fails to tell patients of the lack of safety and efficacy evidence, and fails to tell them that extended use can lead to infections at the insertion site.

> the tracings alone, they will simply adjust the current MDI regimen. If you are there, you'll get Opps. (A311-313)

187. One reason the iPro scheme is so successful is that Medtronic inserts itself as part of the infrastructure of the provider's office. When Medtronic's sales representatives run the clinics and handle the various procedures, the patients view the representative more like a trusted medical professional. This gives the sales representatives enhanced credibility when they present all of the reasons why the patient would benefit from going on pump therapy. Medtronic sought to exploit this trust to convert the "Opps" into sales.

188. When Relator first began conducting iPro clinics in doctors' offices in 2008, he was accompanied by a Diabetes Clinical Manager ("DCM") – a Registered Nurse employed by Medtronic – who would handle all medical aspects of the procedure, including insertion of the sensor device under the patient's skin. To insert the sensor under the skin, a large needle is inserted. A button is pushed which launches the needle and inserts the sensor. The sensor is then adjusted and taped down, and the needle removed from the skin.

189. Beginning in July 2010, his District Manager Mike Ware insisted that Relator handle the iPro procedure alone, without the assistance of an RN. The main reason for this change is that Medtronic wanted the sales representatives, trained in selling pumps, to be the main point of contact with the patients.

190. In an email on October 14, 2010, Relator confirmed with Mr. Ware that he was directed to "become part of the office on a weekly, or bi-weekly basis" and that the "The WIFM (what's in it for me) for the doctor's office . . . .We free up office staff."

191. This practice of having the sales representative become the trusted

medical professional in the patient's eyes is particularly abhorrent. The iPro sensor insertions are medical procedures, involving sticking needles into the recommended insertion points, often the upper pubic area and the upper buttocks. Not only are sales representatives not licensed to perform these procedures, they are ill-equipped to handle any potential complications (such as excessive bleeding or a patient fainting). More atrociously, the patient does not consent to this gross invasion of their privacy, and is unaware that the insertion is being performed by someone who is not licensed or qualified to perform the procedure (nor that the entire opportunity is funded by the supplier and is geared to make a sale).

192. Sales representatives that handled the iPro clinics by themselves, without the assistance of an RN, were commended by Medtronic management, and their practices were held out as "Best Practices." One such sales representative was Kendall Cook, a Territory Manager in the Portland, Oregon. Mr. Cook was featured at one District-wide meeting in January 2011 and gave a presentation to the group on his best practices. At that meeting, Mr. Cook stated that he handles the iPro clinics without a DCM present. One of his main accounts for iPro clinics is Adventist Diabetes Center in Portland, Oregon.

193. The iPro Economic Model was extraordinarily successful in generating new pump sales for Medtronic produced sales results, and became a driving force for Medtronic to increase sales.

194. A Medtronic sales and marketing report, dated February 2011, reflects that "iPro clinics generated over 40% of all new pump sales." In FY 2011, Medtronic's sales goal was to sell 81,000 pumps.

195. As stated by Relator's District Manager in a 2010 Field Coaching Report, "iPro Clinics are the foundation of our business to deliver NPT."

196. In Medtronic's "Train the Trainer" Binder, the purpose of the iPro Economic Model is clearly spelled out "iPro →pump finder →NPNP."

197. Medtronic was well aware of, and tracked the link between its iPro Economic Model and sales. In a marketing campaign launched in FY 2010, it states: "In accounts where iPro is used consistently, a patient is nearly 2.5 times more likely to get started on insulin pump therapy vs. those accounts that use iPro intermittently or not at all."

198. In its "Step by Step: training manual for iPro Clinics, Medtronic makes clear that the sales representatives are to "Present Economic Value" to providers (or, as illustrated on their slide, "Show Me The Money!") in exchange for its primary purpose for offering this economic value: "Get them to Sign in the Line Which is Dotted," the Medtronic order form.

199. Many success stories attributable to the Economic Model were circulated within Medtronic. For example, during a Regional Sales Meeting, the Senior Territory Manager in the Sacramento East Territory described a success story involving Dr. Caruso in Reno, Nevada. Dr. Caruso's office was in "economic trouble – cutting back on staff and hours." After presenting the Economic Model and showing the doctor how much money could be made on iPro clinics, the office started "consistently performing 4 iPros per week" and this put the "Nurse and MA [medical assistant] back to full time employment."

200. By way of another example, according to a Medtronic marketing brochure,

Dr. Thomas Blevens in Austin, Texas owns 30 iPro devices and conducts three iPro clinics a week, each with six patients. Over the course of a year, that would generate an estimated $200,000 for Dr. Blevens. Another heavy user of iPro clinics is Dr. Brian Berelowitz, an endocrinologist in Las Vegas, Nevada. According to a March 29, 2010 email from a Medtronic representative in his area, his office "performs between ten and fifteen iPros per week."

201. To increase the number of iPro clinics as much as possible, Medtronic sales representatives encourage physicians to put their MDI patients through an iPro clinic every time the patients have their "A1c" levels checked, which is typically four times a year. The A1c test (also known as HbA1c or glycated hemoglobin) indicates a person's average blood glucose level over several months and is considered a good general measure of diabetes care. The standard of care for MDI patients is to have their A1c checked every three months. There is no medical reason for MDI patients to go through an iPro clinic every time their A1c is checked, and sales representatives only make this recommendation to give doctors a way to make more money, which further ingratiates the sales representative with the office.

3. Above Fair Market Value Payments for Training.

202. Another of Medtronic's strategies for offering and paying remuneration to increase insulin pump sales involves paying providers above fair-market-value ("FMV") payments to train diabetes patients on the use of Medtronic insulin pumps.

203. These payments are intended to and do induce physicians and others to recommend Medtronic insulin pumps and supplies.

204. Medtronic's sales of insulin pumps consist of (1) sales to new patients and

(2) sales of replacement models or upgrades to existing patients.

205. During the time that Relator worked for Medtronic, the company had contracts, called "Center Contracts" with doctors' offices, diabetes centers, and independent Certified Pump Trainers ("CPT") to pay them to "train" patients on the use of Medtronic's insulin pumps, both new pumps as well as replacement or upgrade pumps. A CPT is typically a Registered Nurse or Registered Dietician that has received further training to become a Certified Diabetes Educator ("CDE"). Medtronic's contracts with its diabetes trainers provided for the following payments:

a. For new patients, Medtronic paid $50 an hour for up to two hours of "pre-pump" training; $225 for pump "start-up" training (paid as a flat rate, no minimum time required); and $50 an hour for up to two hours of "follow-up" training, for a total of $425.

b. For current pump users purchasing a replacement an upgrade model, Medtronic paid $225 for pump "start-up" training (paid as a flat rate); and $50 an hour for up to two hours of "follow-up" training," for a total of $325. If the replacement or upgrade was provided at Medtronic's expense (such as an in-warranty malfunction or a Pathway upgrade), Medtronic paid nothing for training.

206. As explained below, the $225 flat rate payment for "start-up" training is a kickback disguised as a training payment to induce and reward doctors and CPTs for recommending Medtronic pumps and referring diabetes patients to Medtronic.

207. With regard to new patients, Medtronic knows that two hours of "pre-pump" training, paid at $50 per hour, is more than enough time to train the patient on all aspects of the pump and its use and care. Most trainers complete the patient's training during those two hours and simply bill Medtronic for the $225 "start-up" training without providing any further training, or at most a minimal amount of additional training. Many

patients take advantage of Medtronic's free website training even before they see a trainer and learn virtually everything they need to know about the pump before their first training session.

208. Medtronic makes no attempt to monitor the time actually spent by diabetes trainers because the point is not to pay them for services rendered but to reward or induce them to recommend Medtronic's products. Some trainers combine the two hours of pre-pump training and the "start-up" training into a single session of less than two hours, and receive $325 from Medtronic. Sometimes the trainers even combine the pre and post-training with the start-up training and bill Medtronic for the full $425 for one session of training. In all of these circumstances, Medtronic's payment is well above the fair market value of the services rendered and constitutes a reward or inducement to the recipient for recommending Medtronic's insulin pump.

209. For many diabetes centers, the training fees literally kept them in business. These centers are normally staffed by RNs and RDs, and they do not have a physician to bill under. Medicare reimburses RNs and RDs for diabetes training under G-Codes that pay a very nominal amount, less than $20 – not enough to pay the center's bills. Medtronic told these diabetes centers that if they found new pump patients for Medtronic, Medtronic would pay for the pump training at above fair market value rates, $425 per patient. This arrangement allowed many diabetes centers to keep their doors open. Medtronic made clear to them, however, that they would eat what they kill, *i.e.,* that they would need to find the pump patients that Medtronic would pay them to train. This was a powerful financial inducement to these centers to refer pump patients to Medtronic.

210. Even more egregious than the payments for new patient training, however, are Medtronic's payments for "replacement" or "upgrade" pump training.

211. During the time Relator worked for Medtronic, the company paid for replacement pump training even if the patient was put on the same exact pump. Obviously no training is required in those circumstances. Even when the patient receives an upgrade, *i.e.*, newer model, very little training is needed since the changes in models are relatively minor. Nevertheless, Medtronic still paid doctors' staff and qualified trainers $225 for "start-up" training on a replacement or upgrade models, plus $50/hour for two hours of follow up, for a total of $325. The purpose of this payment was to reward and induce the recipients to recommend Medtronic's pumps to their patients.

212. Medtronic pitched the "training" fee to doctors as a way to hire an extra PA, RN or CDE. If an office did enough pump trainings during the year, Medtronic's training payments could pay the salary of the new staff person, who would only have to devote a few hours a week to these trainings.

213. The fact that the training payment is a kickback is reflected in the different way that Medtronic handled training when a replacement model was provided at Medtronic's expense (such as an in-warranty malfunction). In those circumstances, Medtronic paid nothing for training. This is because Medtronic did not want to incentivize in-warranty replacements. For these patients, Medtronic only offered online training or training over the phone with a Medtronic representative

214. Likewise, Medtronic paid nothing for training when a patient obtained an upgrade model through the "Pathway" program. "Pathway" was a program that

Medtronic set up to allow a pump wearer with an in-warranty pump to upgrade to a newer model by paying a few hundred dollars (Medtronic's cost) rather than the retail price. The Pathway upgrade did not come with a new warranty, *i.e*., the warranty of the original model was applied to the upgrade. In these circumstances, Medtronic paid nothing for training, even though Medtronic paid $325 for training when a patient received the exact same upgrade if the upgrade was purchased at the full retail price.

215. In early 2011, Medtronic decided to reign in the payments for replacement training. The company decided to stop paying $225 for "start-up" training for every replacement pump, but left intact the payment for two hours of follow-up training at $50/hour.

216. In or about January 2011, Medtronic informed offices with which Medtronic had contracts for pump training of this new policy. Medtronic informed them that going forward patients purchasing replacement pumps would receive their start-up training by attending a webinar, or that Medtronic would call them and train them over the phone. This change in policy reflects the fact that the previous practice of paying $225 for start-up training was gratuitous and intended as an inducement and reward.

217. In response to this change, the Endocrinology Department of the Bend Memorial Clinic in Bend, Oregon ("Bend Clinic"), one of Medtronic's largest customers in Oregon, threatened to stop recommending Medtronic's insulin pumps to its patients if Medtronic stopped paying the $225 start-up training payment. The clinic stated: "For the last four and half years the process has been that our clinic has completed the upgrade teaching for our patients that we manage on Medtronic insulin pumps and our clinic is reimbursed $225 for insulin pump upgrades." The clinic representative then expressed

"concern that it [stopping the payment] would definitely lead us to seriously consider choosing other insulin pumps for our patient population."

218. Faced with this response, the Medtronic District Clinical Lead agreed to continue the payments:

> I have addressed your concerns with our inside teams and due to how the contract reads now we are going to continue to honor how things have been reimbursed historically for Bend Memorial Clinic. I really appreciate your candid communication regarding this and hope that we can continue to partner with you and your patients.

219. Medtronic's payments were vastly above the CPT reimbursements calculated by Medicare for patient training which, for example, reimbursed certified providers approximately $54.70 (increased from $23.45) and $18.69 (increased from $12.99) per 30 minutes in FY 2011. Medtronic illustrates this price differential by providing physicians a Fact Sheet showing the reimbursements offered by government payors.

220. An example of this is a pump training paid by Medtronic performed by a nurse at Oregon Health Services University on August 31, 2005. This individual conducted a large number of trainings for Medtronic, and on that particular day, billed for pre-pump training (at $100), pump operation & safety (aka, pump start) (billed at $225), and follow-up training (billed at $100), for a total of $425. Based on Relator's experience, this training comprised approximately less than two hours of work.

221. The purpose of Medtronic's payments for training was to induce pump orders from providers.

4. <u>Medtronic's Provision of Other Free Items and Services</u>.

222. Medtronic also offers and pays other types of remuneration in exchange

for the ordering of its products.

223. For example, through its "Nurse in the Office" program, Medtronic provides free nursing services to doctor's offices. Medtronic's purpose in providing these free services is to gain better access to the offices' diabetes patients. Medtronic uses this ploy with very competitive accounts or those in which Medtronic only has limited access to the patients.

224. Each sales territory has at least one Medtronic DCM (Diabetes Clinical Manager), who is a licensed nurse. The DCM travels around the territory and provides free diabetes health care. In certain target offices, the DCMs will offer to establish set office hours, one or more days a week. For offices that accept this offer, the "nurse in the office" quickly becomes viewed as an extension of the office staff. In that capacity the DCM gains access to patients and patient records. Medtronic expects its DCMs to provide the Medtronic sales representatives with information about potential pump candidates for sales purposes.

225. Medtronic has hired nurses to work full-time in large accounts in order to take over the diabetes programs in the accounts. For example, Relator is aware of this happening in a large account in Seattle. Medtronic's objective is to capitalize on the access in order to convert more patients to Medtronic's insulin pump. If Medtronic pays a nurse a salary of $65,000, for example, it only takes approximately seven new pump sales (including revenue from the pump, sensors, supplies, and accessories) to pay the nurse's salary.

226. Medtronic also provides remuneration in the form of loaner iPro devices. Medtronic calls these loaners "demo" devices. Medtronic tells the doctors' offices that

they can bill for the iPro clinics using the demo devices as long as they own at least one iPro device themselves. Relator's territory had 14 iPro demo devices. Three of these devices were expired, but that did not stop Medtronic from using the devices on patients. The three expired devices came from the corporate office. When the company has expired products, rather than disposing of them, it routinely provides them to the sales representatives to use as demo products. This was the case with the three expired iPro demo's as well as a later corporate shipment of demo insulin pumps and transmitters. The field sales force was not told that the demo units were expired. Providing the sales force with expired demo devices is a reckless and unsafe practice, since it encourages use of expired products on patients.

227. Another avenue of remuneration that Medtronic provided was to offer free lunch and dinner programs. Each Territory Manager and District Manager had a marketing budget for the purpose of offering incentives to providers. TM's had approximately $25,000/year budgeted for this purpose, and the District Managers had much more. Among other things, sales representatives could use this budget to purchase iPro units and sensors to offer to providers and patients.

228. In addition, Medtronic's promotional partners also provided budgets for marketing activities, including for the purpose of offering incentives to providers. For example, Eli Lilly provided Medtronic with a budget for lunches and other promotional offers as part of its alliance with Medtronic to market insulin for use with the pump. Relator was instructed by his District Manager that his Lilly counterpart had $1000 to spend for "collaboration lunches." Relator was directed to utilize these resources with his target providers.

229. Medtronic also offered remuneration with its “Connect the Dots” (CTD) Program. The CTD program began when Medtronic joined forces with Lifescan (Johnson & Johnson) to co-promote the Lifescan blood glucose meter that communicates with Medtronic's pump. Lifescan gave Medtronic marketing dollars to pay for this program as part of a deal to be Medtronic’s exclusive meter provider. Medtronic handed out free Lifescan meters at the clinics (even though this is a prescription product) and when iPro clinic patients received a new pump, it came with a new Lifescan meter.

230. For accounts which did not agree to set up an iPro clinic, Medtronic gave another try via the Connect the Dots program.

231. The inducements to doctors’ offices to participate in the CTD program included free travel and accommodations to attend iPro symposiums at luxury venues for not only the doctors but also members of their staff, free or discounted sensors, free text books and other gratuities, binders and handouts on reimbursement, and many other items.

232. For example, one introductory letter to the CTD program identifies several of the gratuities the HCP will receive for participating in the CTD program, including “an iPro demonstration kit, a 4-pack of sensors, a diabetes textbook, and the opportunity to submit a Professional CGM case study for publication in a peer reviewed journal.”

233. Medtronic performed Return on Investment (ROI) analyses and tracked attendees of the iPro symposiums and the CTD accounts to determine how these programs impacted the NPT sales. Medtronic saw huge gains in NPT sales in these accounts. Relator recalls seeing slides showing the increase in NPT in the 30 to 40%

range among attendees of the Las Vegas iPro Symposium he attended.

234. The CTD program co-ventured with Lifescan ended when that partnership ended several months ago, but aspects of its free incentives continued.

235. Medtronic also directed its sales force to target providers for incentives so that they could influence additional referrals to Medtronic. For example, Dr. Ravurri, a provider in Coos Bay, Oregon, was not a diabetes specialist, but was incentivized by Medtronic to enter into a Center Contract and let Medtronic run iPro clinics. Based on this arrangement, Medtronic was able to get other local doctors to refer their insulin requiring patients to Dr. Ravurri (including through paid lunches and other marketing programs). Dr. Ravurri would prescribe, sense, and order pumps, and then refer patients back to their original providers. Referrals to Dr. Ravurri included many pediatric pump patients.

236. Medtronic offered these promotional incentives with the purpose of inducing orders of its products.

B. Medtronic's Kickback Scheme Resulted in the Submission of Materially False Claims.

237. As alleged more specifically in Section VI infra, Medtronic knew that its practices resulted in claims to government healthcare programs, and that those claims were subject to the conditions of payment of those programs.

238. Medtronic is aware that compliance with the AKS and Stark Statute are a material condition of payment of all claims to government healthcare programs.

239. Medtronic's kickbacks and illegal remuneration arrangements with the prescribers for items and services for government healthcare beneficiaries with diabetes would have a natural tendency to influence the Government's decision to pay the

resulting claims.

240. Medtronic's remuneration scheme was intended to, and did, result in claims to government healthcare programs, including without limitation:

- Claims for professional GCM, including claims for physician services submitted by physicians under codes 92250 and 92251, and E&M codes 99212-99215;
- Medtronic pumps and supplies ordered by physicians and billed by Medtronic (or its agent);
- Claims for insulin used with Medtronic pumps, ordered by physicians and billed by the entity dispensing the insulin;
- Claims for training under codes G0108 or G0109 billed by the certified trainer.[8]

241. Every claim submitted to government healthcare programs as a result of Medtronic's remuneration arrangements constitutes a false and fraudulent claim in violation of the federal and state False Claims Acts

242. Representative examples of claims resulting from Medtronic's illegal remuneration schemes include:

Pt. Initials[9]	Approximate Date of Service	Provider Name	Location	Payor	Order
BE	9/28/2005	Michaels, Rodny, M.D	Salem, OR	Medicare	Training
MD	8/25/2006	Gullen	Unk.	Medicaid	Training
DB	12/30/2005	Garrison, Cort	Heppner, OR	Medicare	Training
DT	Unk.	Carroll, Nancy	Bend, OR	Medicare	Training
EE	7/31/2006; 8/17/2008	Countiss, Spencer J.	Grants Pass, OR	Medicare &	Training

[8] Of note, as discussed above, a significant amount of training was instead paid by Medtronic at higher rates.

9 All patient names in this filing are redacted to protect the patient's privacy. Names can be later provided, as appropriate, pursuant to a qualified protective order under HIPAA.

				Medicaid	
GD	1/26/2006	McCarthy	Bend, OR	Medicaid	Training
GD2	Unk.	Unk.	Unk.	Medicare	Training
JP	1/31/2006; 2/25/2011	Palmer, Derek	Unk.	Medicare	Training
KJ	3/31/2006	Gallen, John	Unk.	Medicare	Training
MD	8/25/2006	Gullen	Unk.	Medicaid	Training
PG	3/24/2006	Garrison	Heppner, OR	Medicare	Training
RW	8/2/2006	Kelly	Medford, OR	Medicare & Medicaid	Training
AT	Unk.	McCarthy	Bend, OR	Medicaid	Ipro
LK	12/3/2010	Olsen, Neil	Central Point, OR	Medicare	Ipro
MM	4/13/2006	Jacobson, Kirk	Unk.	Medicare	Ipro
MR	11/5/2009	Eddy, Richard	Unk.	Medicare	Ipro
MM	Unk.	Olshausen, Kai	Unk.	Medicare	Ipro
SM	Unk.	McCarthy	Redmond, OR	Medicaid	Ipro
SA	11/29/2010	Jacobson, Kirk D., M.D.	Eugene, OR	Medicare	Ipro
TW	12/1/2010	Krishnamurthy, M.D.	Unk.	Medicare	Ipro
DB	12/30/2005	Garrison, Cort	Heppner, OR	Medicare	Ipro and Pump
LK	12/3/2010	Olsen, Neil	Central Point, OR	Medicare	Ipro and Pump
SA	11/29/2010	Jacobson, Kirk D., M.D.	Eugene, OR	Medicare	Ipro and Pump
AK	10/27/2010	Ravuri, Rajesh, M.D.	Coos Bay, OR	Medicaid	Pump
AW	Unk.	Sherman	Albany, OR	Medicare	Pump
AS	9/21/2005	Taggart, Phillip	Northridge, CA	Medicare	Pump
BE	9/28/2005	Michaels, Rodny, M.D.	Salem, OR	Medicare	Pump
BV	2/17/2011		Bend, OR	Medicare	Pump
CW	8/2/2010	Pardini, Aaron, M.D.	Harrisburg, OR	Medicare	Pump
CP	Unk.	Krishnaumurking	Unk.	Medicare	Pump
CW	Unk.	Carroll	Bend, OR	Medicare	Pump
CF	5/10/2011	Hap	Corvallis,	Medicare	Pump

			OR		
CP	Unk.	Huang, Chuck	Unk.	Medicaid	Pump
CM	Unk.	Schandelmeier, Gregory	Unk.	Medicare	Pump
CU	Unk.	Michaels	Salem, OR	Medicare	Pump
DH	9/22/2010	Ravuri, Rogesh	Coos Bay, OR	Medicare	Pump
DD	Unk.	Miller	Unk.	Medicaid	Pump
DL	Unk.	Theen	Medford, OR	Medicaid	Pump
DV	7/29/2009	Mendoza	Unk.	Medicare	Pump
DT	Unk.	Calder	Eugene, OR	Medicare	Pump
DK	Unk.	Miller, Eden	Sisters, OR	Medicare	Pump
EF	10/14/2005	Jacobson, Kirk D., M.D.	Eugene, OR	Medicare	Pump
EP	2/17/2011	Carroll, Mary	Bend, OR	Medicare	Pump
EH	Unk.	Cirullo	Unk.	Medicare	Pump
EM	Unk.	Goldstein	Brad, OR	Medicare	Pump
ET	Unk.	Conrad, Christopher	Unk.	Medicare	Pump
EE	7/31/2006	Countiss, Spencer J.	Grants Pass, OR	Medicare & Medicaid	Pump
ES	11/11/2009	Oksenholt, Erling	Unk.	Medicare	Pump
EG	7/23/2010	Kelly, Alan	Unk.	Medicare	Pump
EJ		Carroll, Mary	Bend, OR	Medicare	Pump
FK	1/24/2008	Unk.	Unk.	Medicare	Pump
FH		Goldstein, Rick	Bend, OR	Medicare	Pump
FS	3/29/2005	Cirullo, Ronald, M.D.	Unk.	Medicare	Pump
FW	2/25/2011	Cirullo, Ronald, M.D.	Unk.	Medicare	Pump
GC	1/1/1999	Farmer, Jane	Unk.	Unk.	Pump
GD	1/26/2006	McCarthy	Bend, OR	Medicaid	Pump
GD	Unk.	Unk.	Unk.	Medicare	Pump
GP	Unk.	Fillingame, Raph	Unk.	Medicare	Pump
JB	Unk.		Sweet Home, OR	Medicare	Pump
JD	Unk.	Phillips, Jason		Medicare	Pump
JE	Unk.	Abacan	Roseburg, OR	Medicare	Pump

JY	Unk.	Goldstein	Unk.	Medicaid	Pump
JC	Unk.	Garrison	Unk.	Medicaid	Pump
JP	1/31/2006	Pamer, Derek	Unk.	Medicare	Pump
JN	Unk.	Cirullo, Ronald, M.D.	Unk.	Medicare	Pump
JH	1/25/2005	Bergstron, Richard	Unk.	Medicare	Pump
JT	Unk.	Bradley, Mark	Unk.	Medicare	Pump
JB	11/10/2009	Ganter, Peter	Unk.	Medicare	Pump
JB	Unk.	Wallis, Chris	Unk.	Medicare	Pump
JR	12/7/2010	Ravuri, Rogesh	Coos Bay, OR	Medicare	Pump
JC	2/25/2011	Katz, Vern	Unk.	Medicaid	Pump
JC	Unk.	Jacobson, Kirk D.	Eugene, OR	Medicare	Pump
JS	7/29/2009	Gallen	Unk.	Medicare	Pump
JR	Unk.	Britch, Barbera	Unk.	Medicare	Pump
JH	4/14/2005	Theen, James	Unk.	Medicare	Pump
JT	4/11/2006	Eddy	Medford, OR	Medicare	Pump
KS	11/11/2009	Heinz, Susan	Unk.	Tricare	Pump
KC	11/12/2009	Bassett, Martin	Unk.	Medicare & Medicaid	Pump
KQ	3/30/2005	Michaels, Rodney	Unk.	Medicare	Pump
KJ	3/31/2006	Gallen, John	Unk.	Medicare	Pump
KD	7/30/2009	Phillips	Coos Bay, OR	Medicare	Pump
KB	Unk.	Bassett, Martin L., M.D.	Salem, OR	Medicare	Pump
KC	9/21/2005	Garrison	Medford, OR	Medicare	Pump
LP	Unk.	Pardini	Eugene, OR	Medicaid	Pump
LH	Unk.	Krishmurthy, Priva	Salem, OR	Medicaid & Medicare	Pump
LH	8/2/2010	Michaels, Rodney	Harrisburg, OR	Medicare	Pump
LL	1/22/2008	Unk.	Unk.	Medicare	Pump
ML	Unk.	Pungan	Unk.	Medicare	Pump
MK	8/8/2006	Farmer, Jane	Unk.	Medicare	Pump
MT	11/15/2010	Bassett,	Salem, OR	Medicaid	Pump

		Martin, M.D.			
MR	Unk.	Bentson, Lynn	Unk.	Tricare	Pump
MB	Unk.	Aby-Daniel, Diana	Unk.	Tricare	Pump
ML	Unk.	Katz, Vern	Eugene, OR	Medicaid	Pump
MH	Unk.	Nelson, John	Eugene, OR	Medicare	Pump
ND	8/8/2005	Carroll; Harris, Michael	Bend, OR	Medicare	Pump
PM	Unk.	Cirullo, Ronald, M.D.	Unk.	Medicare	Pump
PD	4/15/2005	Krishnamurking	Unk.	Medicare	Pump
RW	Unk.	Bassett, Martin	Bend, OR	Medicare	Pump
RJ	5/10/2011	Carroll, Mary	Bend, OR	Medicare	Pump
RH	2/25/2011	Chamberlin, Thomas	Unk.	Medicare	Pump
RM	2/25/2011	Britsch, Barbara	Unk.	Medicare	Pump
RG	Unk.	Gallen, John	Salem, OR	Medicare	Pump
RS	9/22/2010	Kelly, Alan	Coos Bay, OR	Medicare	Pump
RC	Unk.	Chamberlin, Thomas	Unk.	Medicare	Pump
SR	Unk.	Carroll	Bend, OR	Medicare	Pump
SB	7/29/2009	Ford, John	Unk.	Medicare	Pump
SG	Unk.	Eddy	Medford, OR	Medicare	Pump
SA	11/29/2010	Jacobson, Kirk D., M.D.	Eugene, OR	Medicare	Pump
SB	Unk.	Palmer	Unk.	Medicare	Pump
SI	Unk.	Abacan	Roseburg, OR	Medicare	Pump
SD	1/18/2011	Daniel, Diana	Unk.	Medicaid	Pump
ST	Unk.	Britsch, Barbara	Unk.	Medicare	Pump
SP	Unk.	Unk.	Eugene, OR	Medicare	Pump
TM	4/13/2005	Miller, Eden	Unk.	Medicaid	Pump
TW	11/10/2009	Jacobson, Kirk	Unk.	Medicaid	Pump
TL	11/20/2009	Merrick, John	Unk.	Medicare	Pump
TD	3/23/2010	Kelly, Alan	Unk.	Medicare	Pump
TM	Unk.	Carroll	Bend, OR	Medicare	Pump

TE	Unk.	Carroll, Mary	Bend, OR	Medicare	Pump
TR	Unk.	Krishnamuthy, Priya	Unk.	Medicaid	Pump
VS	Unk.	Michaels, Rodney	Unk.	Medicaid	Pump
VK	1/25/2008	Manchamp	Unk.	Medicare	Pump
VM	1/9/2008	Unk.	Unk.	Medicare	Pump
WF	10/28/2009	Nelson, John	Eugene, OR	Medicare	Pump

243. Representative examples of providers who Medtronic offered and paid illegal remuneration with the purpose of inducing the ordering of items and services paid for by government healthcare programs include:

I-Pro Clinics

- Dr. Erik Kline, West Olympia Internal Medicine (Olympia, WA)
- Dr. Christina Orr, Vancouver Clinic (Vancouver, WA)
- Dr. Michael Decker, Vancouver Clinic (Vancouver, WA)
- Dr. Elizabeth Stephens, Providence Health Services (Portland, OR)
- Legacy Emmanuel Medical Center (Portland, OR)
- Dr. Nancy Kurosh (Portland, OR)
- Dr. Richard Kirkpatrick (Longview, WA)
- Dr. Anthony Fritz Chehalis, Centralia Specialty Center (Centralia, WA)
- Beth Schwenk, CDE, Providence Seaside, Seaside Dieticians and Nutritionists (Seaside, OR)
- Dr. Shelley Hartman (Hillsboro, OR)
- Dr. latha Radhakrishnan (Salem, OR)
- Dr. Krishnamurthy (Salem, OR)

Individual Providers Offered and Paid Training Contracts:

- Sara Hohn (OHSU, Portland, OR)
- Susan Amidon (Medford, Oregon)
- Jacque Corey (Eugene, Oregon)
- Rita Shearer (Redmond, Oregon)
- Sue Humiston (Sisters, Oregon)
- Teresa Martisak (Medford, Oregon)
- Joy Cook (Medford, Oregon)
- Debbie Pauls (Corvallis, Oregon)

Provider Groups Offered and Paid "Center Contracts":

- Cascade Health Solutions (Eugene, OR)
- St. Charles Diabetes Center (Redmond, OR)
- Bend Memorial Clinic (Bend, OR)
- Dr. Theen (Medford, OR) (Is he a Center or Individual Provider Contract?)
- Institute of Diabetes and Endocrinology (Medford, OR)
- Asante Diabetes Center (Medford, OR)
- Black Oak Clinic (Medford, OR)
- Good Samaritan Hospital (Corvallis, OR)
- North Bend Medical center (Coos Bay, OR)
- Sky Lakes Medical Center (Klamath Falls, OR)
- The Samaritan Lebanon Community Hospital (Lebanon, OR)
- Firehouse Diabetes Center (Salem, OR)
- Peace Health (Eugene, OR)
- Physician's Building (Salem OR)

244. The above are just representative examples. As reflected in a marketing document created on August 20, 2009, Medtronic targeted numerous physician targets for its kickback schemes, including:

Physician	**Provider**	**Location**	**Key Influencer**	**Medtronic Listed Marketing Tactics**	**Additional Notes from Medtronic**
	Joslin Diabetes Center	Boston, MA	Kristi Shavor; Zoryana Moreau	What we can offer to patients… technology, giveaways, futures.	New technology, small basal rate, new sets, giveaways for peds.
Flesner, Kelly, M.D.	Oklahoma Heart Institute	Tulsa, OK	Kelly Flesner, M.D.; Eric Asperson	Physician has a large elderly/medicare population and wants a color screen, larger fonts, etc	KOL speaking engagement in territory;

Physician	Provider	Location	Key Influencer	Medtronic Listed Marketing Tactics	Additional Notes from Medtronic
Habas, Joellen, M.D.	Cherokee Diabetes Program	Cherokee, NC	Joellen Habas, M.D.	Insurance coverage and Financial Assistance programs.	Dr Habas is new to Cherokee but has had good experience with Medtronic in past. She is interested in IPT for her pts but cost is huge issue. they just switched to BCBS NC and has coverage now. very large opportunity because up until now they have had no pump coverage. large % have medicare/Medic aid also.
Jain, Rajinder, MD		Troy, NY	Tracy Kueh, RN, CDE	Partnership with provider to meet the needs of his patients	MD has a part-time RN, CDE (Tracy Kuehn) who does all his education/pump starts. Tracy is a "key" influencer of which pump patient starts on for therapy
Hakim, Majd, MD	Frederick Memorial Hospital	Frederick, MD	Kathy Kissane	patient selection, nyc classes, stop offering choice	
Kaye, Zachary, M.D.	Potomac Hospital Diabetes Center	Woodbridge, VA		NYC or IPro Clinics	
Corsi, Christopher, M.D.	Western Montana Clinic at Broadway Building	Missoula, MT	Carla Cos	Showing her the future technologies at a home office visit.	

Physician	Provider	Location	Key Influencer	Medtronic Listed Marketing Tactics	Additional Notes from Medtronic
Vaccarello -Cruz, Mary, M.D.		Palm Beach, FL		Teach physician and staff how to manage therapies that provide revenue	Dislikes MDT marketing practices wants to be only influencer with patients
	Southern New Hampshire Endocrinology/Joslin Affiliate	Nashua, NH	Robert Silver	Awarding more clinical trials to this practice	
	OU Medical Center	Edmond, OK	Lisa Rogan	Customer Visits and Clinical Trials	They have in the past used mostly Deltec and now mostly Omnipod because of the Omnipod rep being a past employee of Oklahoma.
	Diabetes and Endocrinology Center of Western CT, Danbury Hospital	Danbury, CT	Dr. Robert Savino, D.O.	Participation in clinical studies	Dr. Savino is the Chief of Endocriology and is taking on more of a Administrative role. The Hospital is undergoing a transformation to become a "Center" to compete with Yale.

Physician	Provider	Location	Key Influencer	Medtronic Listed Marketing Tactics	Additional Notes from Medtronic
	Cooper Endo	Cherry Hill, NJ	Karen Weiss	Several issues: 1) Money for trainings 2) Waterproof pump 3) Smaller basal/bolus rates 4) Color Screen 5) Bad blood with CDE and Manager/Medtronic	The higher amount paid for trainer is definitely an issue
	Endocrine Consultants NW	Tacoma, WA	Dali Chen, MD	Local Program for their office	
	ECU Brody School of Medicine	Greenville, NC	Robert Tanenburg, Almond Drake, Sylvester Odeke, Mohammad Dar	IPro Clinics	
Charlotte McCloughlin				Ipro Clinics, Carelink Downloads, Now You Can classes	No see doctors; CDE is new to practice, pro-medtonic.
	John Muir Endocrine Group - Concord, CA	Concord, CA	Anna Chang, MD; Genevieve Yue, MD	Clinical research/trials. Dr Chang wants us to provide her with Guardian units free of charge, as supposedly Dexcom did, to evaluate the Guardian's effectiveness	Access to knowledge of, or use of, new pumps - each time she see me, she asks when are we going to come out with a new pump. She also tells me that our technology is outdated and that we need to do what Omnipod is doing!

Physician	Provider	Location	Key Influencer	Medtronic Listed Marketing Tactics	Additional Notes from Medtronic
Reiner, Barry, M.D.	Barry J. Reiner	Baltimore, MD	Nicholas Argento, MD	Smaller sensor with greater lower level accuracy	
	Dartmouth Hitchcock Medical Center - Adult and Pedi	Lebanon, NH	Rita Ketay; Carol French	Free resources... i.e. sensors, and ipros	Dexcom has given this account 15 free units to use on their patients; and many patients end up buying the Dexcom after using it.
	Suburban Endocrinology	Arlington heights, IL	Dr. Soruco	IPRO reimbursement with BCBS IL PPO. Type 2 IPT advocate.	Having Medtronic do IPRO's, have Medtronic provide services to assist with help. We've offered both and they are hesistant.
	All Childrens Hospital Endocrine		Dorothy Shulman	reimbursement info for ipros, sensors, etc	They own 5 Ipros
Weiser, Kenneth, MD		White Plains, NY	Mary Joan Olko NP Jonathan weinstein MD	showing what if any patch pump technology we have and cost of omnipod taken as a whole	
Weiss, Stuart, MD		New York, NY		tubeless pump	

Physician	Provider	Location	Key Influencer	Medtronic Listed Marketing Tactics	Additional Notes from Medtronic
	University of Minnesota Adult Endocrinology			Continued information on new products, sensor information, closed loop technology	Dr. Bantle is a strong advocate for Medtronic. He has the majority of their patients on our pump/sensor combination and is a strong advocate for his patients to receive this therapy. He has gone head to head with Adele regarding her steering patients towards other products. Unfortunately his colleagues rely on her for everything where he manages his patients himself.
Mellman, Michael, MD		Boynton Beach, FL		Doctor perceives his practice to be extremely busy needs a program for which there is honoraria that will allow him to step away from his practice to learn something new that can benefit his practice	again program needs to provide honoraria in order to get the prescriber outside of the office; Only uses MDT and Animas; has been "burned" by lack of support from Deltec and will not presribe Omnipod
Schmeltz, Ralph, MD		Washingt on, PA		Speaking opportunities; educational programs	

Physician	Provider	Location	Key Influencer	Medtronic Listed Marketing Tactics	Additional Notes from Medtronic
	Diabetes and Thyroid Treatment Center		Dianne Roland; Chris Law	offer to allow wearing of therapy for free (he wears Medtronic)	speaking agreements, etc

245. By way of example, in January, 2009, District Manager Travis Allen scheduled several new iPro clinics for providers in Ft. Worth. He stated:

> We have five clinics that will give us access to their starts each week. Each clinic has at least three i-Pros. That is 15 starts a week. 10 of them should become Opps. This can give you and (sic) additional 40 Opps a month). Mondays are reserved for selling new iPro (Gluck, Castro, Endo Assoc, Baylor, Dunn…)

The providers targeted for selling new i-Pros were Endocrine Associates, Baylor Internal Medicine, Cook Children's, and Drs. Ashai, Gluck and Castro. The providers that had I-Pro clinics were Health First, Plana Medical , Medical Associates, NETIMA, and Kotha CGM Clinic. Medtronic was aware that its provider targets served government healthcare beneficiaries.

246. By way of further example, the marketing document created on August 20, 2009, identified above, also reflects this knowledge. For instance, for Dr. Kelly Flesner, it is noted "Physician has a large elderly/medicare population and wants a color screen, larger fonts, etc." For Dr. Joellen Habas, it is noted "very large opportunity because (sic) up until now they have had no pump coverage. large % have medicare/medicaid also."

247. Finally, Relator is aware that Dr. Radhakrishnan, who was later replaced by Dr. Krishnamuthy, at Physician's Building, had a large Medicare population. Medtronic had exclusive access to their patients and received 100 percent of their

business.

248. Defendants' kickback schemes have been occurring since at least 2004 and are on-going.

III. Medtronic Caused the Submission of False Claims for Ineligible and Unnecessary Orders for Pumps for Type 2 Patients.

A. Medtronic's Push For Type 2 Patients on the Pump.

249. As described above, Medtronic's corporate strategy was focused on "expanding indications" for its insulin pump, and breaking into the Type 2 market as a replacement for conventional injection therapy for insulin-dependent patients.

250. However, Medicare only covers infusion pumps for a very limited subset of Type 2 patients. The patients must satisfy strict criteria, including, among others: (1) "a documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump" and (2) a fasting C-peptide level that is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method, along with a concomitant fasting blood sugar less than or equal to 225 mg/dl. Other government insurance programs follow similar guidelines to determine patient eligibility for insulin pump therapy reimbursement.

251. These requirements are difficult to satisfy for the majority of Type 2 patients.

252. In 2004, Medtronic requested that CMS remove the C-peptide testing as a criterion for coverage of insulin pumps. In its request, Medtronic identified that hundreds of Medicare patients per year failed to meet the C-peptide criteria.

253. After careful analysis of the clinical evidence, CMS rejected the

suggestion that it should loosen its standards for coverage of insulin pump therapy and issued a detailed Decision Memo regarding its coverage decision. CMS specifically identified that the majority of elderly diabetics who are government healthcare beneficiaries are Type 2, and that there is a lack of clinical evidence regarding the use of insulin pumps in that population. *Id.*

254. CMS concluded, based on the general consensus of the literature and review of expert opinions, that the "use of the [insulin pump] is rarely indicated in [Type 2 patients] and that strict criteria should be used for eligibility." CMS December 17, 2004 Decision Memo, *citing*, among others, NICE Technology Assessment and Aetna Clinical Policy Bulletin #0161.

255. Notwithstanding its failed attempt to expand the coverage of the insulin pump by government payors, Medtronic established a national sales strategy to expand its sales of insulin pumps to the Type 2 market.

256. As discussed in the previous section, Medtronic was wholly focused on transforming MDI patients (traditionally Type 2 patients) to pump therapy. It wanted to increases its new pump patient sales (referred to as NPT) and gave sales representatives minimum requirements regarding their conversion of NPT's per month.

257. As illustrated on its "Therapy Driver Account Profile," a training material reflecting best practices: "For an account to maximize its potential, it must understand and believe in all of the indications of pump therapy, promote the therapy to *all insulin requiring patients*, and *not limit the therapy to specific patient types*." (Emphasis added) Further, Medtronic identifies that that one of its end goals is that "HCP [healthcare provider] promotes IPT [insulin pump therapy] as the standard of care for *all insulin-*

requiring patients." (Emphasis added)

258. In another email dated October 2009 describing best practices, District Manager Ware states: "Expand Indications. Type II is a very large, under-served segment…" and regarding iPro clinics: "focus on indications with the HCP, not just a single patient."

259. Medtronic directed its sales force to expand indications in the Type 2 market using a number of different incentives and misleading schemes.

260. Notwithstanding the conclusions of CMS that pump therapy was rarely indicated for Type 2 patients, Medtronic set out to convince providers to prescribe the pump for all its Type 2 patients.

261. As further described in the Section IV below regarding its illegal promotional activities, Medtronic used misleading sales aides and antidotal examples to dupe physicians into expanding the indication for pump therapy into their MDI patients. For example, Medtronic would mock up "studies" of small groups of patients, would then coach those patients into perfect compliance by Medtronic, and then use the supposed positive results to convince physicians that all his or her Type 2 patients would have similar results with pump therapy (*see, e.g., infra* ¶ 327.c).

262. One of the most overt ways in which Medtronic attempted to falsely induce Type 2 claims was to coach the patients to skew the data supporting the patient's eligibility for pump therapy.

B. <u>Medtronic's Misrepresentations Regarding Type 2 Eligibility</u>.

263. Notwithstanding the Medtronic's mandated nationwide push was to expand indications for its pump to Type 2 patients, these patients were still largely

ineligible for pump therapy.

264. In order to obtain these orders anyway, Medtronic made false representations to providers and, in turn, to government healthcare programs regarding the appropriateness of Type 2 patients for pump therapy.

265. During the time that Relator worked for Medtronic, it was a routine practice to prepare or cause the preparation of false statements and records certifying that patients meet these eligibility criteria when they do not in fact meet the criteria.

266. Medtronic has the opportunity to engage in this misconduct because Medtronic typically assists patients in submitting applications for insurance coverage of Medtronic products. Most patients sign an "Authorization/Assignment of Benefits" form that authorizes Medtronic to submit patient information to the insurer.

267. To gather relevant patient information, Medtronic requires patients to fill out a health questionnaire providing sufficient information to verify that the patient satisfies the criteria for eligibility under the Medicare Guidelines. Patients rarely fill out the questionnaire on their own. They are encouraged to contact a Medtronic sales representative or call Medtronic's 24 hour telephone center helpline to assist them in filling out the questionnaire. The telephone helpline is staffed by Medtronic Diabetes Therapy Consultants ("DTCs") and Diabetes Therapy Associates ("DTAs").

268. Even in the rare instance in which the patient does fill out the health questionnaire on his or her own, Medtronic invariably contacts the patient and starts over in order to make sure the questions are answered in an optimal manner to receive insurance coverage. The health questionnaire is easy to change because it has no space for a signature by the patient; therefore it can be revised any number of times

without resubmitting it to the patient for a new signature. The only document that the patient signs is the Assignment/Authorization of Benefits form, which is on a separate sheet from the health questionnaire. Medtronic submits the health questionnaire together with the AOB to the insurance company.

269. A Medtronic representative typically fills out the health questionnaire for the patient while speaking with the patient, either in person or over the phone, and gives it or faxes it to the patient to sign.

270. Medtronic then pre-populates a Certificate of Medical Necessity (sometimes called the Letter of Medical Necessity) certifying that the device is medically necessary and that the patient meets the criteria for use of the device, and faxes it to the doctor's office for signature.

271. In Relator's experience, most MDI patients cannot meet the Medicare requirement that they have a "documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump." "Documented" means documented in the patient's medical records or chart notes.

272. The Medtronic sales representatives and helpline staff are trained in techniques to elicit from patients the statement that they meet the self-testing requirement even when they do not. There are many such techniques. For example, the patients are told that they will only obtain insurance coverage if they answer "yes" to certain questions, and they quickly get the picture and provide the "right" answer. Because the health questionnaire is not signed, patients are generally willing to go along with this charade and provide the "right' answer even when they know it is false. Some Medtronic representatives answer the questions without even asking the patient.

273. Medtronic also trains all of the CPTs, diabetes centers, nurses, and medical assistants that do business with Medtronic in these same interview techniques. They generally comply because they get paid by Medtronic when a pump sale is made (for example, by receiving training fees, see section VI.B.1 *supra*); and equally importantly, if the answers are wrong and insurance coverage is denied, it will be their responsibility to appeal the determination and gather the necessary documentation, as well as deal with the angry patient.

274. One reason this fraudulent scheme works so well with Medicare is because Medicare does not require prior authorization to approve an insulin pump. Medicare relies upon the certification of the patient and physician that the patient meets the eligibility criteria.

275. In contrast to Medicare, many other insurers require Prior Authorization before covering an insulin pump. As part of the approval process, these insurers routinely check the patient's medical records to determine if the patient has a documented record of self-testing glucose levels four times a day. In Relator's territory in Oregon, Medtronic has a very low success rate, much less than 50%, in getting coverage for the pump when an insurer requires Prior Authorization and checks for documentation of self-testing.

276. To obtain insurance coverage from insurers that require Prior Authorization, some Medtronic sales representatives, desperate to meet their sales quotas, have resorted to coaching patients to fabricate blood glucose logs. Logs are easy to fabricate since they can be as simple as a piece of notebook paper with four blood glucose numbers written down per day. The pressure on sales representatives to

meet their quotas is so intense that many engage in fraudulent practices like these in an effort to hold onto their job.

277. In December 2010, Relator's Manager, Mike Ware, sent an email to the sales force in the Pacific Northwest District warning them that they needed to tell the truth when submitting information to the insurers that require Prior Authorization. Mr. Ware's email is telling because it does not contain a similar warning about information submitted to insurers that do not require Prior Authorization (such as Medicare). Mr. Ware's email states:

> The reason for this email is to provide you insight on how our DTA counterparts will be handling the PA [Prior Authorization] process for Regence (WA & OR), Premera [sic.], and First Health. We have received several denials for RTS [the Real-Time System insulin pump] over the past few months. The denials have been a result of documents (office notes, bsl [blood sugar level], hypo events [hypoglycemic events]) not matching the LMN [Letter of Medical Necessity].
>
> Protocol for Regence of WA, Regence of OR, Primera and First Health:
> - Request office notes and BSL (Fax 1)
> - Compile LMN with accurate information
> - Request signature of LMN (Fax 2)
> - Submit for Prior Authorization
>
> [Emphasis added]

278. No attempt was made to change the company's protocol with regard to Medicare, because it rarely conducts an audit to verify the submitted information. Medtronic's practice with Medicare was, and continues to be, to falsify the information submitted to Medicare in order to qualify MDI patients for insurance coverage for pump therapy.

279. Medtronic also coaches patients on how to falsify the results of their fasting C-peptide test. C-peptide is a byproduct created when the hormone insulin is

produced by the pancreas. The C-peptide test is an indicator of how much insulin is being produced by the pancreas.

280. As noted above, Medicare Guidelines require that the patient's "[d]iabetes needs to be documented by a fasting C-peptide level that is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method." The C-peptide level that is less than or equal to 110 percent of the lower limit of normal is typically a C-peptide level at or below 70 or 80 ng/mL (nanograms per milliliter).

281. The reason that Medicare includes the C-peptide test in its eligibility criteria for an insulin pump is to determine if the pancreas is still functioning. Medicare does not want to pay for pump therapy, which is very expensive for Medicare, if the pancreas is still functioning.

282. In 2004, Medtronic launched a campaign to convince CMS to remove the C-peptide requirement from the Medicare Guidelines, but this effort was unsuccessful. After losing that battle, Medtronic began coaching its customers in methods to produce low C-peptide test results in order to meet the Medicare Guidelines.

283. The first method that Relator was taught, by his manager at the time (Doug Villiers), was to instruct patients to go on a carbohydrate fast for several days before the C-peptide test. Relator felt pressure from his manager to follow this instruction and therefore did so.

284. For example, one patient in Oregon, whose initials are G.D., initially took the fasting C-peptide test and the result was approximately 3.0 mg/dL, over 300% higher than the low end of normal. After G.D. followed Relator's instruction to carbohydrate fast for several days, he passed the test with a score of approximately .6

mg/dL.

285. Relator recalls having considerable success with this technique. Relator believes that the majority of physicians and diabetes educators in his District are now routinely using this technique without concern due to Medtronic's promotion of the technique.

286. More recently, Relator was instructed on another method to manipulate the C-peptide test. Relator learned this method at Medtronic Minimed's headquarters in Northridge, California on a Customer Visit Program. Managers from across the country were at the meeting.

287. During the meeting, Rudy Thoms, a District Manager in the Michigan area, told the assembled group of a "foolproof" method that he had been using for a long time. Mr. Thoms explained that the method involves inducing hypoglycemia, since a C-peptide test during a hypoglycemic episode will always be well below normal because there is no insulin production at that time (and therefore no C-peptide production), even in a normal pancreas.

288. Mr. Thoms explained the method in some detail. The patients are instructed to go to the testing lab, and while there inject themselves with an overdose of insulin. Then the patients self-test their glucose level to confirm hypoglycemia, and then take the blood draw for the C-peptide test, which invariably will show a C-peptide of less than 1.1 times normal levels. The patients stay in the testing facility drinking a juice box until blood glucose levels come back up to a safe level.

289. Mr. Thoms told Relator that the company had been coaching patients and providers on this method for some time. Mr. Thoms has since been promoted to a

managed care position within Medtronic.

290. Relator also learned about this same technique from Mike Ware, who became Relator's District Manager in July 2010. Before assuming that position, Mr. Ware had been a Territory Manager in Colorado. Mr. Ware told Relator that getting a pump candidate to pass the C-peptide test was a piece of cake. He instructed Relator to do exactly as Mr. Thoms had instructed Relator a few years earlier.

C. Medtronic's Scheme Resulted in the Submission of Materially False Claims.

291. As alleged more specifically in Section VI *infra*, Medtronic knew that its practices resulted in claims to government healthcare programs, and that those claims were subject to the conditions of payment of those programs.

292. Government healthcare programs restrict coverage of pump therapy to only those patients who meet the specified eligibility requirements.

293. Government healthcare programs also restrict coverage of medical devices to those that are reasonable and necessary. Claims for medical devices are not reasonable and necessary when they are not safe and effective, exceed the patient's medical need, or serve essentially the same purpose of equipment already available to the beneficiary.

294. Failure to satisfy these requirements would have a natural tendency to influence the Government's decision to pay the resulting claims.

295. Similarly, Medtronic's false statements regarding the safety, efficacy, and/or need for a Type 2 patient to convert from MDI therapy to pump therapy (a therapy that Medicare has restricted to a subset of patients) are material to payment of the resulting claim.

296. Each claim for reimbursement caused by Medtronic's fraudulent conduct constitutes a false and fraudulent claim in violation of the federal and state false claims acts.

297. Representative examples of claims resulting from Medtronic's material representations regarding the eligibility of the patient for coverage include:

Pt. Initials	Approximate Date of Service	Provider Name	Location	Payor
GD		Theen, James, M.D.	Medford, OR	Medicare
LS	1/17/2011	Bassett, Martin L., M.D.	Salem, OR	Medicare
RS	7/28/2010 (fax)	Kelly, Alan		Medicare

298. Representative examples of providers who relied on Medtronic's material misrepresentations relating to the eligibility of patients for pump therapy include:

- Dr. John Gallen, Medford, OR
- Dr. Krishnamurthy, Salem, OR
- John Nelson, Eugene, OR
- Dr. Radhakrishnan, Salem, OR
- Dr. Mary Carroll, Bend, Or
- Dr. Pardini, Eugene, Or
- Dr. Kirk Jacobson, Eugene, OR
- Dr. James Theen, Medford, or
- Dr. Richard Eddy, Medford, OR

299. These fraudulent schemes have been occurring since at least 2004 and are on-going.

IV. Medtronic Caused the Submission of False Claims for Drugs and Medical Devices for Noncovered and NonPayable Off-Label Uses.

A. Medtronic Promotes its Insulin Pump Off-Label for Use with High Potency U-500 Insulin.

300. In the United States insulin is sold in two strengths: U-100 and U-500. U-100 insulin contains 100 units of insulin activity per mL of fluid. U-500 is five times more concentrated and contains 500 units of insulin activity per mL of fluid.

301. Medtronic has a joint venture with Eli Lilly & Co. ("Lilly") to market Lilly's insulin. Lilly sells both U-100 insulin and U-500 insulin. Lilly is the only manufacturer of U-500 insulin. Its U-500 insulin is called Humulin R U-500.

302. Because of the high potency of U-500 insulin, extreme caution must be taken to avoid overdosing on it. The FDA has only approved U-500 insulin for subcutaneous injection, and not for use in insulin pumps. The FDA-approved Prescribing Information ("P.I.") for Humulin U-500 insulin, the only brand of U-500 insulin approved by the FDA, states: "Humulin R U-500 is for subcutaneous injection only."

303. Because the risks of dosing confusion with U-500 insulin are so great, even when used in a syringe (its on-label use), in March 2011 the FDA ordered that additional safety warnings be added to the P.I. for Humulin U-500. The new warnings state:

> **PRECAUTIONS**
>
> **Dosing Confusion/Dosing Errors**
>
> Medication errors associated with Humulin R U-500 have occurred and resulted in patients experiencing hyperglycemia, hypoglycemia or death. The majority of errors occurred due to errors in dispensing, prescribing or administration.

304. Likewise, Medtronic's insulin pump is approved by the FDA for use with U-100 insulin only, and not for use with U-500 insulin. On each occasion that Medtronic has applied to the FDA for approval for one of its insulin pumps, Medtronic has represented that the pump is only intended for use with U-100 insulin, and the FDA has approved the product on that basis. A representative example is the May 21, 2004 FDA approval of the Medtronic Paradigm Model 515/715 Insulin Pumps. The FDA approved the pumps based upon Medtronic's representation that the pumps "are designed to deliver 0.00 to 35.00 units of U100 insulin per hour in basal rates and up to 25.00 units of U100 insulin per meal or meal bolus." (emphasis added).

305. Notwithstanding these restrictions, and in reckless disregard of patient safety, Medtronic is promoting use of its insulin pump with U-500 insulin for obese and insulin-resistant Type 2 diabetics. Medtronic's conduct causes off-label prescriptions to be written for both the insulin pump as well as the U-500 insulin.

306. Medtronic's primary motivation for engaging in this unlawful conduct is the desire to sell more insulin pumps to patients with Type 2 diabetes. Historically, Medtronic has sold very few pumps in this segment of the market because insulin-dependent Type 2 diabetics are typically overweight or obese, and therefore require large amounts of insulin, often several hundred units a day. Medtronic's largest insulin pump only holds a maximum of 300 units of U-100 insulin, which renders the pump impractical for these patients since they would have to change the reservoir constantly, instead of every 3 days (as is the case with patients with Type 1 diabetes).

307. Medtronic viewed U-500 insulin as the solution to this problem. When U-500 is placed in a pump with a 300 unit reservoir, the pump can hold the equivalent of

1500 units of U-100 insulin, rather than merely 300 units.

308. Beginning in or about 2007, Medtronic began promoting its insulin pump with U-500 insulin to insulin-dependent Type 2 diabetics, in blatant disregard of the scope of the FDA's approval of both of these products.

309. Medtronic knew that the target population would be susceptible to this off-label promotional practice for two reasons. First, as previously discussed, going on pump therapy generally saves Medicare patients money because it shifts the cost from his or her prescription drug plan under Medicare Part D (covering MDI therapy at a higher out of pocket cost) to Medicare Part B (covering pump therapy with a co-pay).

310. Secondly, obese Type 2 diabetics, as a class, generally have a poor record of adhering to complicated insulin injection regimens. For these patients, going on pump therapy is superficially attractive because it relieves them of having to self-administer multiple daily injections of insulin.

311. However, there is a good reason why U-500 insulin is not approved for use in Medtronic's insulin pumps for *any* patient population: It creates serious health risks for patients.

312. The first risk is dosing confusion. All of the measurements on Medtronic's insulin pump are in units of U-100 insulin. The pump does not have the ability to convert to units of U-500 insulin. If U-500 insulin is substituted for U-100, the user must remember to divide by five the insulin units displayed on the pump. For example, if the patient needs 20 units of U-100 insulin, he/she must divide the pump's recommended dose by five and just take four units of U-500 insulin. If the patient does not remember and takes 20 units, the patient will have actually dosed 100 units.

313. Since most recommended dosages are in tenths of a unit, the math becomes even more complex. For example, if the recommended dose from the pump is 23.25 units of insulin, the correct does of U-500 insulin is 4.65 units. Patients can easily make a calculation error (or forget to divide the number by five entirely). A mistake in calculation creates significant risk of overdosing.

314. The risk of overdosing with insulin is that it will bring the glucose levels down too low, resulting in hypoglycemia. For example, if an individual using U-500 insulin in the pump intends to deliver a bolus dosage of 150 units of insulin and forgets to set the dosage meter on 1/5th of that amount, the pump will deliver the equivalent of 750 units of insulin. Such an overdose can cause extreme hypoglycemia. Extreme hypoglycemia can cause loss of consciousness and even death.

315. The risk is so significant that the FDA included U-500 insulin in the FDA's 2008 first quarterly report of drugs with "potential safety issues." The FDA listed the safety issue as "dosing confusion."[10] The FDA reiterated the risk of dosing confusion in another report, entitled "Mixups between Insulin U-100 and U-500," in the Sept. 2008 edition of "FDA Patient Safety News."[11]

316. A second health risk from substituting U-500 for U-100 insulin in the pump stems from the fact that U-500 insulin has a different time action profile than certain brands of U-100 insulin. The time action profile of insulin is defined by its onset, peak and duration. Onset refers to how long it takes to start working; peak refers to how long

[10] This report can be viewed on the FDA's website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm085914.htm.

[11] This report can be viewed at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=79.

it takes to reach its peak concentration; and duration is how long it lasts in the body.

317. The U-100 insulin that is used in insulin pumps is called “rapid acting” insulin. (The leading brands are Lilly’s Humalog, Novo Nordisk’s Novalog, and Sanofi-Aventis’s Apidra.) Rapid-acting insulin works quickly: its onset is almost immediate, it peaks quickly (30-90 minutes), and is out of the body quickly (within four hours). In contrast, the only brand of U-500 insulin sold in the United States, Humulin R U500 (jointly marketed by Lilly and Medtronic), is “regular acting” insulin, not “rapid acting” insulin. Regular acting U-500 insulin has a slower time action profile than rapid-acting U-100 insulin. This creates the potential for pump users who switch from U-100 to U-500 insulin to have prolonged hypoglycemic reactions due to the drug staying in the system much longer than U-100 insulin. Also, bolus dosing methodology in a pump is calibrated for rapid-acting insulin, but U-500 has a delayed activity, making it more difficult to determine the correct bolus dosing. These nuances add considerable complexity and greater risk of misdosing when U-500 insulin is substituted for U-100 in the pump.

318. This risk has, in fact, led to Adverse Events, which illustrate the risks of using U-500 in an insulin pump.

319. On February 13, 2005, a patient using U-500 insulin in a Medtronic insulin pump experienced an FDA-reported Adverse Event. According to the Adverse Event report, the patient was hospitalized for low blood glucose levels. The company determined that “[t]he programming, insulin concentration and bolus history were not accurate.”

320. On March 5, 2011, a patient using U-500 insulin in a Medtronic insulin

pump experienced an FDA-reported Adverse Event. According to the Adverse Event report, "It was reported that the customer was treated in the emergency room due to hyperglycemia, with blood glucose readings over 500 mg/dl. . . . The customer . . . stated that he recently had changed to u500 insulin from the u100 insulin and that has changed his averages. . . . The customer further stated that he had only given himself manual boluses instead of using the bolus wizard. Nothing further was reported."

321. Other patients using U-500 insulin in other manufacturer's insulin pumps have also experienced Adverse Events, because the same risks are present when using U-500 off-label.

322. For example, in approximately December 2009, a patient using U-500 insulin in an insulin pump manufactured by Animas Corp experienced an FDA-reported Adverse Event. According to the Adverse Event report, on the date of the incident the patient:

> woke up in an ambulance after passing out on the floor. The pt's blood glucose was around or below 30 mg/dl and was treated at the hospital. He indicated that the incident was related to the insulin he was using at the time. The pt was using u500 insulin when the pump was designed for u100 insulin. He indicated that after he switched to u100 humalog, his bg [blood glucose] was fine. There is no indication that the pump malfunctioned; however, this complaint is being reported because the pt reportedly became hypoglycemic and required medical intervention when he used u500 insulin with the pump.

Notably, the manufacturer's response included that the pump was designed for U-100.

323. On January 30, 2006, a patient using U-500 in an insulin pump manufactured by Smith Medical (formerly Deltec, Inc.) experienced an FDA-reported Adverse Event. According to the Adverse Event report, the:

> patient had become unresponsive on 01/30/06 due to hypoglycaemia and the paramedics had to be summoned. The patient's md reported that the patient uses u-500 humulin regular insulin in his insulin pump. . . . The md believed this [adverse event] to be the result of an incorrect calculation of insulin based on his correction formula. The doctor was informed [by the manufacturer] that the device was only labelled to be used with u100 insulin."

Notably, the manufacturer's response included that the device was only labeled to be used with U-100 insulin.

324. On October 27, 2010, a patient using U-500 insulin in an insulin pump manufactured by Animas Corp experienced an FDA-reported Adverse Event. According to the Adverse Event report, the patient was hospitalized due to inadvertent infusion of insulin. The manufacturer responded to the report of the event by stating, inter alia, that "[t]he pump is not indicated for use with u500 insulin."

325. Simply put, use of U-500 in an insulin pump has not been demonstrated to be safe and effective for medical use. In contrast, Medtronic's Product Manuals for each of its Insulin Pumps state that the pump is intended only for use with U-100 insulin. A representative example is the Product Manual for the MMT-523/723 insulin pump, which states at page 47:

> The Paradigm pump is intended for use with U100 insulin. The following insulins have been tested by Medtronic MiniMed and found to be safe for use in Paradigm REAL-Time insulin pumps (MMT-523, MMT-723, MMT-523K, and MMT-723K):
> • Humalog
> • Novolog

(emphasis added).

326. There have been no FDA findings of safety and effectiveness of this use, nor is there any substantiating clinical data to support clinical safety and effectiveness. The off-label uses of U-500 and the pump described herein are not supported by

demonstrations that the unlabeled use of the drug and device is safe and effective and in accordance with nationally accepted standards of practice.

327. Despite these health risks and without presenting the FDA with any evidence that its pumps are safe and effective with U-500 insulin, Medtronic is actively promoting the use of U-500 insulin in its pumps to obese and insulin resistant Type 2 diabetics. Medtronic's management condones and encourages this off-label promotional practice. Following are examples:

a. Medtronic distributes to doctors and patients a conversion chart entitled, "Conversion Chart for Use of u500 Insulin in Pump Set for u100 Insulin Concentration." The distribution of this chart facilitates and encourages the use of U-500 insulin in the insulin pump.

b. Medtronic provides its Territory Managers with copies of the Prescribing Information ("P.I.") for U-500 insulin and instructs them to distribute it to the physicians in their territories unsolicited. Relator received his copy of the P.I. from his District Manager, who received it from the Regional Sales Director Mike DiGiulio. As instructed, Relator emailed the P.I. to all of the diabetes health care professionals and diabetes educators in his territory. Relator's forwarding email stated, "Many people have requested information on U500. Here is some information from its manufacturer." Because Medtronic's Territory Managers sell diabetes pumps but do not sell insulin, the recipients of this email would have understood that the email related to insulin pumps. For example, Dr. John Gallen sent a reply email asking for information on the use of U-500 in Medtronic's insulin pump. Relator's DCM, Chris Makinson, visited Dr. Gallen's

office to discuss this subject, and as a result Dr. Gallen put patients on the Medtronic pump using U-500 insulin.

c. In 2009, two Medtronic employees in the Pacific Northwest District – Territory Manager Cathy Anderson and DCM Jennifer Minahan, RN – persuaded a Seattle endocrinologist, Dr. Shaista Quddusi, to conduct an informal study in which the doctor put 12 of her Type 2 diabetes patients on pump therapy, seven of whom used U-500 insulin in the pumps since they needed high dosages of insulin. Prior to the informal study, the doctor did not put Type 2 patients on the pump. Due to the coaching the patients received from the DCM, all of the patients showed improvement. In using these informal "studies," Medtronic ensured that the patients studied produced good results on the pump with close instruction and monitoring not available to the average Type 2 patient on the pump. As plainly shown by Medtronic's coverage criteria, the compliance behaviors of the patient are key to the success of pump therapy. Thus, the coaching of these informal "studies" produces misleading results regarding the appropriateness of Type 2 patients for the pump.

d. The two Medtronic employees were highly commended by senior management for this initiative, and the company disseminated the findings of their "study" throughout the region and the nation. Ms. Anderson and RN Minaham made presentations of their findings at District Sales Meetings and at a National Sales Meeting. By disseminating these findings and commending their initiative, Medtronic's clear message to the sales force was to follow their lead and put more Type 2 patients on pump therapy with U-500 insulin. Medtronic rewarded Ms. Minaham for her role in this initiative by promoting her to a leadership position in charge of all of the DCMs in

the Pacific Northwest District. She was promoted by Mike DiGiulio, Regional Sales Director.

e. When disseminating the findings of the informal study conducted by Ms. Anderson and RN Minaham, however, Medtronic largely ignored the challenges encountered during the study of determining proper dosing of U-500 insulin in the pump. In an email to her District Manager on August 27, 2009, Territory Manager Cathy Anderson acknowledged that:

> U500 was a bit of a challenge. It is regular insulin so it peaks 3-5 hours later. Basals were increased at higher rates during the day to help with food and drop basals overnight because dinner insulin peaks in the middle of the night and put them at risk for nocturnal hypos. Basal was more 60% and bolus 40% and thank god for Carelink [the pump software]! The u500 pts called into the clinic weekly for the first month. Other than that you treat it like 5x stronger insulin.

In another email on the same day, Ms. Anderson conceded that dosing with U-500 was partially guess work: "All u500 users in the pump take more [insulin] if you calculate out units, which I don't know if that is accurate or appropriate? Anyway the results so far are great!" Despite the uncertainties with dosing, the company proceeded full steam ahead with these U-500 patients on the pump. Moreover, on the same day where she acknowledged dangerous risks such as "nocturnal hypos" and that patients had to call into the clinic weekly due to confusion, she did not report these difficulties back to the doctor. Instead, she wrote Dr. Quddusi, who prior to the study had not prescribed the pump for Type 2 diabetes patients, and provided the favorable statistical outcomes with a conclusion that "[a]nyway the results so far are great!" Her conclusions were misleading as she did not provide the information regarding the challenges presented to

the U500 patients. Nor did she reveal how closely coached the patients were, such that they no longer reflected the average Type 2 population.

f. In internal communications within the Diabetes Division, there was very open discussion about using U-500 insulin in the pump. For example, when Ms. Anderson and RN Minahan were preparing a presentation for the District Sales Meeting, Ms. Anderson sent around an email on December 9, 2009, openly stating, " Travis [District Manager] asked Jenn and I to talk at the meeting. He wants us to talk on indications. . . . We were thinking type 2 review and U500 and some case studies . . . ."

g. Medtronic encouraged its employees to talk to groups outside the company about successes with U-500 insulin in the pumps. For example, in January 2009, Ms. Anderson was invited to give a talk to a medical practice in Seattle, Washington. She accepted the invitation and listed one of her intended topics as "type 2 and success with u500."

h. To make physicians more comfortable with the idea of using U-500 in the pumps, the company instructed its sales representatives to provide their physicians with journal articles that made positive references to pump therapy with U-500 insulin. One such article is by Dr. Steven Wittlin, entitled, "Treating the Spectrum of Type 2 Diabetes: Emphasis on Insulin Pump Therapy.," The Diabetes Educator 2006 32: 39S, which states at page 43S:

> Although not approved by the Food and Drug Administration for use in pumps, U-500 insulin can be an alternative in patients who require very large doses. This concentrated form of insulin has been shown by Knee and colleagues in a case series to be effective . . . . [12]

[12] In his article emphasizing the use of Insulin Pump Therapy, Dr. Wittlin fails to disclose that he has served on the advisory board for and has received honoraria and grant/research support from Medtronic. *See,* K. Dugan, et al., *1,5-Anhydroglucitol and Postprandial Hyperglycemia as Measured by Continuous*

Sales representatives were also told to disseminate other articles that advocated use of insulin pump therapy for obese or insulin resistant Type 2 diabetics, such as, Wainstein, J. et. al, "Insulin Pump Therapy vs. Multiple Daily Injections in Obese Type 2 Diabetic Patients," Diabetes Med. 22, 1037-1046 (2005); Nielsen, S., *et al.*, "Use of Continuous Subcutaneous Insulin Infusion Pump in Patients with Type 2 Diabetes Mellitus," Diabetes Educator, November/December 2005, vol. 31 no. 6, 843-848. However, the Wainstein and Nielson articles did not present clinical data but rather were limited studies.[13] Sales representatives misrepresented these articles as clinical data to lead into a discussion with doctors about the treatment of their obese and insulin resistant Type 2 patients – patients that have traditionally been very difficult to treat, and that the sales representatives know will be put on U-500 insulin in the pump if pump therapy is initiated. Sales representatives use the information gained from these discussions to target the physicians' obese and insulin resistant Type 2 patients for pump sales.

i. Company managers routinely circulated to the sales force success stories about putting Type 2 patients on insulin pumps with U-500 insulin. For example, on September 26, 2007, Doug Villiers, then District Manager for the Pacific Northwest District, circulated an email from Territory Manager Ed Stewart recounting his success at persuading a doctor to place a Type 2 diabetic patient on an insulin pump with U-500 insulin. In the underlying email, Ed Stewart explained:

> In an effort to expand indications with Dr. Chen, I asked him his opinions about pump therapy in Type 2 Diabetes with patients who are highly

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Glucose Monitoring System in Moderately Controlled Patients With Diabetes, Diabetes Care, Vol. 29, No. 6, JUNE 2006.

13 Out of 40 patients in Wainstein's study, for example, only 29 finished. Further, only 15 were treated with pump therapy. Nielson only looked at 4 patients.

> insulin resistant. He gave me lots of feedback which was great, and I shared with him some key takeaways from the Nielsen study [cited above], which looks at these specific patients, we discussed the results and I left a copy.
>
> Attached is a copy of an AOB [Authorization of Benefits insurance form signed by a purchaser of a pump] we received from him the NEXT DAY! It is for a 319 lb T2 [Type 2 diabetic], on 8-9 shots of U-500 . . . . (Very much like the patients in the study we reviewed!)

When District Manager Villiers circulated this success story, he commended it as an example of increasing sales by working "to expand indications." This was an apt description – it unilaterally expanded the pump's indications beyond those approved as safe and effective by the FDA and presented a four-patient outcomes case study as clinical evidence of safety and effectiveness. The prohibition against off-label promotion is designed precisely to prevent companies from usurping the FDA's role in this manner.

j. In an email on April 7, 2010, Mike DiGiulio, Regional Sales Director for the Western Region, forwarded to the Western region sales force a March 29, 2010 email from a DCM in Las Vegas, Nevada recounting her efforts to encourage Dr. Brian Berelowitz to prescribe insulin pump therapy for an insulin-resistant Type 2 patient requiring U-500 insulin:

> Dr. Brian Berelowitz is a highly regarded adult endocrinologist here in Las Vegas with a large practice. His office performs between ten and fifteen iPros per week on their patients and the doctor is an advocate for insulin pump therapy for nearly all Type 1 and insulin-requiring Type 2 patients in his practice. . . . I asked him if he could think of anyone who is very insulin resistant, someone he might be thinking of using U500 insulin on.

The Regional Director commended the DCM's initiative and called it a "great . . . success" when he forwarded the email to the Western Region sales force.

328. In February 2011, the FDA scheduled a visit to Medtronic. Medtronic

suspected that the visit was prompted by Relator having alerted the FDA to the company's off-label promotional practices, including promotion of the insulin pump for use with U-500 insulin.

329. Immediately prior to the FDA's scheduled visit, Medtronic quickly put together two "trainings" about off-label promotion. The trainings each consisted of a study guide and a written exam that the sales force was required to take on line. One of the exam questions asked whether the following question by a physician is off-label: "Can my nurse practitioner use U-500 insulin in a Medtronic insulin pump?" The correct exam answer was yes, it is off-label. Another question and answer made the point that a sales representative must refer all off-label questions to the Medtronic Health Affairs division – the first Relator heard of this was in the study guide handed out shortly before the exam was given.

330. These "trainings" were a paltry after-the-fact attempt to make it appear as if Medtronic instructed its sales representatives to comply with the prohibition against off-label promotion, when in fact the company actively encouraged off-label promotion, as the above examples demonstrate.

1. Medtronic Made False Representations to Induce Providers to Use U-500 Insulin in Pumps

331. Medtronic engaged in a variety of false representations in its off-label promotion U-500 and the pump.

332. Medtronic Territory Managers and other employees were trained to, and routinely did, misrepresent that U-500 was safe and effective for off-label use in the pump by:

a. Presenting limited patient outcomes or private practice-run "studies" as

clinical data;

b. Presenting limited patient outcomes or private practice-run "studies" without revealing that the patients were coached by Medtronic nurses and no longer represented a typical Type 2 patient on U-500;

c. Failing to inform doctors of the dangerous difficulties of using U-500 (such as dosing confusion) and failing to inform of adverse events;

d. Presenting U-100 benefits for Type 2 patients, knowing most Type 2 patients would end up using U-500;

e. Claiming to patients and doctors that Medtronic had never had an over-delivery of insulin;

f. Claiming that endocrinologists all over the country are using U-500 in the pump, which was not true when Medtronic began the promotion and misleads the provider into believing it is a nationally accepted practice;

g. Making claims as to efficacy without clinical support.

333. Medtronic Territory Managers and other employees were trained to, and routinely did, misrepresent that U-500 was safe and effective for off-label use in the pump by presenting limited patient outcomes or private practice-run "studies" as clinical data.

334. By way of specific example, Medtronic employees routinely used an article discussing four patient examples (only three of which finished the case study) by Susan Nielson that it presented as clinical data. In September 2007, Diabetes Management Consultant Edward C. Stewart in Tacoma, Washington recounted his success in using this study to successfully convince a doctor to put a patient on the pump using U-500. The District Manager praised his efforts and circulated to the team and recommended the approach as using "clinical data to challenge a Prescriber's belief."

335. By way of further example, in November 2010, there was a regional conference call to review "Tips from the Top" for Insulin Pump Therapy for Type II

Diabetes patients. Prior to the call, the Sales Director for the West Region, Michael DiGiulio, distributed a PowerPoint to be reviewed on the call. In introducing the topic as to "why" Medtronic's employees should focus on Type 2 patients, it noted there were 1.14 million Type 1 diabetics on insulin, compared to 4.18 million Type 2 diabetics on insulin. One slide highlighted suggested "Clinical Evidence" to review with doctors. Among the "clinical evidence" was the Neilson article. Another article the slide referred to as "Clinical Evidence" is by J. Wainstein, who engaged in a limited study. Finally, the slide suggested use of the Wittlin article on Type 2 patients. The slide did not identify, however, that Wittlin has received honoraria and gran/research support from Medtronic.

336. The Medtronic PowerPoint recounted the success story of a Dr. Gutin and noted that all three "clinical articles" were utilized to "emphasize better control & outcomes with CSII". The result was seven new Type 2 patients for the pump with two more "in the pipeline."

337. Further, Medtronic provides a several-inch thick leather bound notebook called the "Site Seller" to its Territory Managers. The Site Seller is the product detail aid of choice from the corporate office and is used by sales representatives with healthcare providers and patients. One of the tabs is for treatment of Type 2 patients. Sales representatives use these slides on sales calls to promote use of the insulin pump with Type 2 patients, knowing that most of these patients, if put on a pump, will use U-500 insulin in the pump. The Nielson and Wainstein articles are prominently presented.

338. Medtronic also distributed a guide at a National Sales Meeting that provided speaking points regarding journal articles and instructed its sales representatives to provide their physicians with journal articles that made positive

references to pump therapy with U-500 insulin or that discussed pump therapy for obese and insulin resistant Type 2 diabetics who, the company knew, would use U-500 insulin if they were placed on the pump. The Nileson and Wainstein articles were again prominently referenced.

339. Medtronic Territory Managers and other employees were trained to, and routinely did, misrepresent that U-500 was safe and effective for off-label use in the pump by presenting limited patient outcomes or private practice-run "studies" without revealing that the patients were coached by Medtronic nurses.

340. By way of specific example, the company disseminated the findings of the twelve patients (seven of whom used U-500 insulin) developed by Medtronic employees Cathy Anderson and Jennifer Minaham in Washington. As referenced above, Ms. Anderson and RN Minaham made presentations of their findings at District Sales Meetings and at a National Sales Meeting. Ms. Anderson also distributed a PowerPoint that showed the success of the results, but did not mention any of the difficulties or challenges encountered with U-500 patients and did not represent that these patients had received special attention and care that the ordinary patient would not.

341. The findings were used as a sales aid to sell U-500 use in the pump to doctors in Relator's territory and others throughout the region. The sales force did not inform the doctors that the patients had to receive intensive diabetes management to ensure they performed well.

342. Part of Medtronic's training was to encourage presentation of home-made studies and other case examples as clinical data of safety and effectiveness. In accounts where Medtronic wanted to "expand indications," the DCM (Diabetes Clinical

Manager) would utilize an excel spreadsheet template called the patient or clinical "outcomes tracker" ("COT") on targeted patients who were new to pump therapy ("NPTs"). In effect, these were sham studies that convinced doubtful prescribers into becoming pump prescribers. The more successful "studies" were then circulated throughout Medtronic to be used in selling the effectiveness of the pump. They were misleading to physicians in that the patients received pampered care that ordinary NPTs would not. Further, the DCMs were not interested in clinical data but rather ensuring "good outcomes" to lead to more sales.

343. By way of example, Jennifer Minahan, Medtronic Diabetes District Clinical Lead, in response to questions regarding whether there were "best practices" for the COTs, provided the following instructions to DCMs on her entire team in an email dated September 1, 2010:

> 1. The DCMs should do the trainings to ensure good outcomes as we know we are way better trainers than our CPTs. I think it's up to you & Michael as to what makes sense for your business but my recommendation would be for the DCM to do the trainings so we can follow them and make sure that outcomes are good.
> ….
>
> 4. Best Practices. To be honest, I'm not sure it's been implemented yet. Mike and I would love to hear COT best practices as this is a GREAT tool that is not being implemented in our district. As a district we really need to step up here. There are territories that are killing their NPT numbers due to the COT...it works!!!

344. This email was then forwarded to all of the Territory Managers in the District by District Manager Mike Ware, entreating them to use the Clinical Outcomes tracker ("COT") for patients new to therapy ("NPT") in order to sell the pump:

> As a TM team need to get involved in the COT with our DCMs. There are TMs blowing it out there NPT because of the COT. Lets make sure that we are not asking for only 6 MDI patients...we need to ask for a minimum

> of 10 to 15. Lets get this implemented with our Big 3 and CAT accounts immediately. It is no additional work for our HCPs and they will have an opportunity to see the benefit of our technology for their patients.

345. By way of further example, after the current model of the pump, the PRT Revel, was approved by the FDA on March 17, 2010, Medtronic provided launch training and provided material referred to internally as the “Revel Yell.” The Revel Yell identified two targets for the pump—patients with Type 2 diabetes and pediatric patients—and provided key selling points. Under a heading entitled "clinical evidence," it listed the "patient outcomes tracker."

346. Medtronic Territory Managers and other employees were trained to, and routinely did, misrepresent that U-500 was safe and effective for off-label use in the pump by falsely presenting U-100 benefits for Type 2 patients knowing most patients would end up on U-500.

347. By way of example, one of the key selling points in converting patients from MDI therapy to the pump was that the pump could use rapid acting insulin instead of intermediate or long-acting insulin. However, for Type II “insulin resistant” patients, Medtronic knew the likelihood would be that the patients would need U-500, and regular acting U-500 has a slower time action profile than rapid-acting U-100 insulin. Thus, the territory managers employed a “bait and switch” tactic—sell the pump’s efficacy by presenting materials regarding the benefits of using rapid acting insulin, then switch the patient to U-500, even though this was regular insulin that acted like intermediate insulin and off-label.

348. By way of further example, one of the homemade sales aids circulated throughout the Western Region was entitled “Which is Truly Easier?” It presents the idea that with the pump it is easier to eat a meal, by listing 5 simple steps necessary for

the pump, versus 11 more complicated steps of MDI. The steps identified for the pump are:

1. Test BG
2. Count Carbs
3. Enter Carbs into pump
4. Push button to calculate entire bolus
5. Push button to deliver insulin

This sales aid was used to target Type 2 patients, who were generally viewed as being less compliant with recommended dosing regimens. However, the sales representatives also knew that the purportedly "easier" features of the pump disappeared with the use of U-500 insulin, which many of these Type 2 patients would be using.

349. Medtronic also encouraged a message that its sales force routinely carried to patients and doctors, namely that Medtronic had never had an over-delivery of insulin. This was part of Medtronic's "safety message" and part of its core competitive message as to "why [choose] Medtronic" over a competitor during the entirety of Relator's employment with Medtronic. This was a national mantra and a message that Relator, other Territory Managers and Medtronic representatives had rehearsed many times.

350. By way of specific example, the Diabetes Management Consultant for Eastern Washington and Northern Ohio, Lisa Johnston, had a form letter to send to customers to convince them to buy a Medtronic pump over a competitor's product. In it, she writes:

> Medtronic Diabetes has been making insulin pumps for over 20 years. Within that time, over 30 different pump companies have come and gone - but we're still here. And in 20 years we have never had an over-delivery of insulin *-not one single time.*

(emphasis in original).

351. However, as outlined in this Complaint, Medtronic has had at least one adverse event reports filed with the FDA regarding over-delivery of U-500 insulin. Also, on July 10, 2009, Medtronic issued a recall for "Lot 8" Quick-set infusion sets, admitting:

> Medtronic recently discovered that approximately two percent of "Lot 8" Quick-set infusion sets (which represents approximately 60,000 infusion sets out of an estimated 3 million infusion sets currently with customers) may not work properly. The affected infusion sets may not allow the insulin pump to vent air pressure properly. This could potentially result in the device delivering too much or too little insulin and may lead to serious injury or death.

http://www.fda.gov/Safety/Recalls/ucm171588.htm (last visited on February 8, 2013).

352. Medtronic Territory Managers and other employees were trained to, and routinely did, misrepresent that U-500 was safe and effective for off-label use in the pump by claiming that endocrinologists all over the country are using U-500 in the pump, which was not true when Medtronic began the promotion and misleads the provider into believing it is a nationally accepted practice.

353. By way of example, Relator and others were encouraged to use the Wittlin article to support their claim that this therapy was common, with remarks such as "look it's showing up in studies." The Wittlin article only remarked that U-500 insulin use in a pump "can be an alternative." Moreover, Wittlin has received honoraria and grant/research support from Medtonic. Territory managers were also told by district and regional managers to state that "big dogs", or key opinion leaders (KOLs) in the diabetes community were using U500 in the pump. Relator, however, is unaware of

whether these KOLs were in fact prescribing U-500 in this manner.

354. Medtronic Territory Managers and other employees were trained to, and routinely did, misrepresent that U-500 was safe and effective for off-label use in the pump by making claims as to efficacy with no clinical supporting evidence, such as claiming by being on the pump, Type 2 patients using U500 could lose weight or claiming that diabetes easier to manage with U500.

355. For example, the November 2010 “Tips from the Top” PowerPoint distributed by Michael DiGiulio presented a “DM2 Case Study” of a Medtronic I-pro client who had weight loss to support its claim that placing patients on a pump leads to weight loss. Territory Managers commonly referenced the Wainstien article as further “clinical” support that weight loss was common. However, as far as Relator is aware, there is no clinical supporting evidence that U-500 in pump therapy leads to weight loss.

356. By way of further example, a homemade detail aid circulated nationwide introduced an internet article from WebMD to use to sell against multiple daily injections for Type II diabetics. Sales representatives were told that this was a great conversation piece to get into a discussion about noncompliant type II diabetic patients whose diabetes was not well controlled. They discussed how these patients might be skipping their injections for economic reasons (insulin is paid for by Medicare if they are on the pump) or for convenience reasons (the insulin is not right there on the patient’s belt). This also led to discussion about U-500 insulin and the fact that often times patients who do take their insulin do not take more than 1 shot at a meal if they require more than 100 units because that would require more than one shot at one time.

357. All of the above-described methods are ways in which Medtronic falsely

represented to prescribers the U-500 insulin as effective and safe for use in its insulin pump.

2. Medtronic's Scheme Resulted in the Submission of Materially False Claims.

358. As alleged more specifically in Section VI infra, Medtronic knew that its practices resulted in claims to government healthcare programs, and that those claims were subject to the conditions of payment of those programs.

359. As a condition of payment, only reasonable and necessary items and services are covered by government healthcare programs.

360. An item or service is not "reasonable and necessary" if it is not safe and effective.

361. Unlabeled uses of a drug are presumptively not safe and effective, and could only be covered in the circumstance that "the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice."

362. Medtronic is aware that U-500 insulin is not approved for use with the pump and that its use is not supported as safe and effective by any major compendia, authoritative literature, or accepted standards of medical practice.

363. Medtronic is also aware that its pump is not approved for use with U-500, and that there has been no examination by the FDA of this intended use.

364. Unlabeled uses of devices have not been supported by the provision of safety and efficacy information to the FDA. Unlabeled uses of devices not supported by evidence of safety and effectiveness are not reasonable and necessary.

365. Medtronic's false representations and omissions to providers regarding

the safety and effectiveness of the use of U-500 insulin with the pump would have a natural tendency to influence the Government's decision to pay the resulting claims.

366. Every claim submitted to the government (1) for a Medtronic insulin pump or (2) for Lilly-Medtronic's U-500 insulin as a result of Medtronic's off-label promotional practices described herein constitutes a false and fraudulent claim in violation of the federal and state False Claims Acts

367. Representative examples of government healthcare claims resulting from this scheme include:

Pt. Initials	Approximate Date of Service	Provider Name	Location	Payor
AK	10/27/2010; 12/8/2010	Ravuri, Rajesh, M.D.	Unk.	Medicaid
TW	12/1/2010	Krishnamurthy, Priya, M.D.	Salem, OR	Medicare

368. Representative examples of providers who were targeted by Medtronic using these practices include:

- Dr. John Gallen, Medford, OR
- Dr. Krishnamurthy, Salem, OR
- John Nelson, Eugene, OR
- Dr. Radhakrishnan, Salem, OR
- Dr. Mary Carroll, Bend, OR
- Dr. Pardini, Eugene, OR
- Dr. Kirk Jacobson, Eugene, OR
- Dr. James Theen, Medford, OR
- Dr. Richard Eddy, Medford, OR

369. These fraudulent schemes have been occurring since at least 2006 and

are on-going.

B. Medtronic Markets Its Adult Insulin Pump For Off-Label Use By Pediatric Patients.

370. Medtronic's Paradigm RT system is an integrated insulin pump and continuous glucose monitoring device. The FDA approved the Paradigm RT system for adult patients (ages 18 and older) on April 7, 2006. The FDA approved a modified system for pediatric patients (ages 7 through 17) on March 8, 2007. There is no integrated insulin pump and continuous glucose monitoring device approved for ages below 7.

371. The insulin pumps in the Paradigm RT systems have alarm settings to alert the user when blood sugar levels rise above a certain level or fall below a certain level. The only difference between the adult and pediatric Paradigm RT systems is in the software settings for the alerts. The FDA required the pump in the pediatric Paradigm RT system to have more conservative settings for the low glucose alert than the pump in the adult system. The FDA insisted on this modification in order to provide pediatric patients with additional warning time to react to potential hypoglycemic (low blood glucose) episodes.

372. The following is the FDA's description of the difference between the adult pump and the pediatric pump in the Paradigm RT system (the letter "k" after a product number denotes that it is approved for pediatric patients):

> The Paradigm MMT-522k and MMT-722k insulin infusion pumps are identical to the previously approved model MMT-522 and MMT-722 insulin infusion pumps (P980022/S013) with the exception of the programmable values available for the pumps' low glucose alarm. The minimum value that may be selected for the low glucose alarm for the MMT-522 and MMT-722 pumps is 40 mg/dL whereas the

software used in the MMT-522k and MMT-722k pumps has been modified to limit the minimum programmable value for the low glucose alarm to 90 mg/dL.

373. In its approval memorandum, the FDA explained why it required a more conservative setting for the low glucose alarm in the pediatric pump as a condition for approval. The FDA explained that in Medtronic's pre-approval clinical studies with pediatric patients, the glucose sensor in the Paradigm RT system provided higher readings than the reference meter (a fingerstick meter) at low glucose levels (levels below 80 mg/dL). Consequently, the FDA determined that it was necessary to set the minimum programmable values for the low glucose alert at 90 mg/dL (as opposed to 40 mg/dL in the adult pump) in order to "increase the probability that the device will alarm in the event of hypoglycemia when these devices are used by children and adolescents."[14]

374. While the low glucose alarm setting in the pediatric pump provides an additional measure of safety, it also creates more frequent alerts. For Medtronic, this was a problem, because pediatric users and their parents complained that the setting was too conservative and resulted in so many alerts as to be annoying.

375. Medtronic did not want to lose customers because of this problem. Pediatric patients are the most valuable customers since they can be expected to be on diabetes products the rest of their lives. Also, parents are willing to buy the sensor for their child regardless of its cost if it will have any chance of normalizing their child's life.

376. Medtronic spent considerable resources to promote the efficacy of the Paradigm RT system for pediatric patients – relying primarily on (1) a Medtronic-funded

[14] FDA Approval Memorandum, "Summary of Safety and Effectiveness Data," March 8, 2007, at p. 6, available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p980022s015

clinical trial involving pediatric patients called the STAR 3 trial and (2) a study done by the Juvenile Diabetes Research Foundation (JDRF) published in the New England Journal of Medicine in 2008,[15] both of which showed the efficacy of the Paradigm RT system for pediatric patients. The company did not want these efforts to be frustrated by the annoyance of the low glucose alert in the pediatric Paradigm RT system. [16] In order to get around this annoyance, Medtronic began selling pediatric patients the Paradigm RT system with the adult insulin pump instead of the pediatric pump (i.e., pump model numbers 523 and 723 instead of 523k and 723k).

377. Shortly after Medtronic received FDA approval for the Paradigm RT system for pediatric patients in March 2007, Medtronic also launched a new transmitter for the system called MiniLink. MiniLink made the product a lot more user friendly and thus received a big launch by Medtronic. As part of the launch, Medtronic provided a webinar session online for health care practitioners. One question and answer in the webinar addressed the simultaneous approval of the pediatric pump, showing that Medtronic was already actively selling the adult pump to pediatric patients:

> Q: Will pediatric patients have to upgrade to the "K" pump to use the CGM, or continue to use their 522/722 pump if they already have it and have been using CGM?
> A: Pediatric patients DO NOT have to upgrade to the K pump to use CGM. They should use whichever pump their doctor prescribes.

[15] The JDRF writing committee responsible for this article includes the following doctors who have paid affiliations with Medtronic: Dr. Tamborlane who receives consulting fees from Lifescan, a partner with Medtronic and receives consulting and lecture fees and grant support from Medtronic; Dr. Bode who receives consulting and lecture fees, travel reimbursement and grant support from Medtronic; Dr. Buckingham who receives lecture fees and grant support from Medtronic and serves on an advisory board for Lifescan; Dr. Fiallo-Scharer who receives supplies for research from Medtronic; Dr. Hirsch, who receives grant support from Medtronic; Dr. Laffel who receives consulting fees from Lifescan and consulting fees and grant support from Medtroinic; Dr. Weinzimer who receives lecture fees and travel reimbursement from Medtronic; Dr. Wilson wo receives equipment, software and grant support from Medtronic; and Dr. Wolpert who receives grant support from Medtronic.

16 Further, Medtronic had to work against a competitive disadvantage in that its pediatric pumps did not as appear visually appealing to kids as its competitors' pumps.

> If their doctor has already prescribed CGM for them and they are already successful on the standard model pump with CGM, there is no reason they need to change. If their doctor wants them to get on the K pump to use the CGM, then they would exchange their 522/722 for a 522K/722K for $299 when they buy the CGM Starter Kit.
>
> Because diabetes treatment is so customized and individualized, we do not have a policy on what pediatric patients will by default receive. It all depends on the doctor's treatment goals and the doctor's prescription. We will fill the order and service whatever product the doctor prescribes.

378. Medtronic strongly encouraged its sales representatives to invite all of their doctors to attend these webinars. Relator, for instance, routinely invited all of the providers in his territory, both physicians and diabetes educators, to attend. A large, national audience of healthcare providers viewed this webinar and learned "there is no reason to change" a pediatric patient to a pediatric pump.

379. This Webinar also makes it clear that prior to the FDA's approval of use of the pump in patients below the age of 18, Medtronic was already promoting off-label use of the pump by pediatric patients. In its Webinar Answer, Medtronic failed to identify that the FDA had found stricter controls were necessary in the alerts to patients below the age of 18.

380. Contrary to its Webinar Answer, moreover, when doctors prescribe the Paradigm RT system for their pediatric patients, the Medtronic sales representatives routinely fill out the necessary paperwork and order the system containing the adult pump. Due to Medtronic's successful false marketing of the adult pump, most health care practitioners are not even aware of the difference between the pediatric and adult insulin pumps.

381. Typically the ordering process works in the following manner. The doctor decides to prescribe a medical device (the Paradigm RT system in this example) for the

patient. The doctor then tells the Medtronic representative to contact the patient. A Medtronic Territory Manager or DTC will call the patient and fill out a health questionnaire based on the information the patient provides.

382. This health questionnaire is then given to a Medtronic DTA, who will verify the patient's eligibility for insurance benefits. The DTA then prepares a Certificate of Medical Necessity ("CMN"), sometimes called a Letter of Medical Necessity ("LMN"), which states that the device is medically necessary and that the patient meets the criteria for use of the device, and faxes it to the doctor's office for signature. Medtronic pre-populates the CMN to order the adult insulin pump, even if it is for a pediatric patient. Doctors, not knowing the difference between the model number for the adult versus pediatric pump, invariably sign the CMN, which is then submitted with all of the other insurance paperwork to the health plan.

383. Internally, Medtronic justifies the sale of adult pumps to pediatric patients on the grounds that it is the physicians' decision to prescribe the adult pump for the patient. This is a sham justification because the physicians rely on Medtronic representatives to assist them with the ordering process, and Medtronic pre-populates the paperwork to select the adult pump for pediatric patients, and does not inform them of the safety and efficacy issues presented by the adult pump.

384. Relator is informed and believes that, as a result of these practices, the vast majority of pediatric patients presently using a Medtronic insulin pump are using the adult insulin pump.

385. By selling the adult pump to pediatric patients in place of the pediatric pump, in order to bypass the more conservative low glucose alarm settings of the

pediatric pump, Medtronic is circumventing the very condition that the FDA established for approval of the pediatric pump in the Paradigm RT system. Off-label sales of the adult pump to pediatric patients places these patients at increased risk of having hypoglycemic episodes – the very risk the FDA sought to avoid by imposing a lower alarm setting on the pediatric pump.

386. Medtronic's disregard of FDA protections for pediatric patients even extends to children under 7, for whom Medtronic's diabetes devices are not approved in any form. The FDA approved Medtronic's pediatric insulin pump for sale to children ages 7 through 17. Similarly, the FDA approved Medtronic's pediatric glucose sensor for sale to children ages 7 through 17. Yet, the company encourages its sales representatives to market the pump and the sensor for use by children under the age of 7.

387. For example, on January 24, 2011, Mike DiGiulio, Regional Sales Director for the Western Region, sent an email to the sales force in the West Region with the subject line, "4yr old giving Bolus - Add this to your iPad!" The email, which was marked "High" Importance, provided a link to a YouTube video showing a four year child using an insulin pump and glucose sensor. The email stated:

> West Region Team,
> Wow, take a look at this powerful video. A 4 year old giving himself a bolus. Please add to your iPads team to use in your discussions with ped accounts. This speaks volumes about the simplest diabetes management system for patients . . . .
>
> http://www.youtube.com/watch?v=I-xWPEzNI_o&feature=youtube_gdata_player

The YouTube video is available for viewing at the above link. The text accompanying the video, written by the child's parent, explains that the child uses a Medtronic insulin pump and glucose sensor.

388. Mr. DiGiulio referred to "iPads" in his email because Medtronic sales representatives now carry iPads into their sales calls to display promotional information on the computer screen. Medtronic encourages its diabetes sales representatives to use their iPads in creative ways to sell Medtronic's diabetes products. DiGiulio had previously given a presentation at the FY 2010 National Sales Meeting on "best practices to reach New Patients," and instructed sales representatives to place the following items, among others, on their iPads:

1. VOE [17]

2. You tube

3. Case Studies[18]

This instruction was tantamount to telling them to use their iPads for off-label promotion. Like the YouTube video with the four-year old, none of these materials have been approved for marketing use by the FDA, and all of them frequently make off-label claims. Territory Managers presented these materials as "clinical evidence" to persuade healthcare providers and patients that Medtronic products were safe and effective.

389. By telling the sales representatives to add the YouTube video to their iPads, Mr. DiGiulio was instructing them to use the video on sales calls with physicians. Showing a physician a video of a four year old using an insulin pump and glucose

[17] The VOE refers to "Voices of Experience," which are testimonials of physicians.
[18] The "Case Studies" refer to homemade materials put together by sales representatives recounting experiences of their customers with Medtronic products.

sensor is a means of promoting these devices for similar patients of the physician. Because the insulin pump and glucose sensor are not approved for patients under seven, such conduct constitutes unlawful off-label promotion.

1. Medtronic Used False Statements in Promoting Off-Label Use of Adult Pump by Pediatric Patients.

390. Medtronic engaged in a variety of false representations in its off-label promotion of the adult pump for use by pediatric patients. Its key strategy was obfuscation by failing to sell the pediatric pump, failing to explain the differences in the pediatric settings to parents and doctors, and in its competitive messaging.

391. One of Medtronic's key methods to selling the adult pump off-label to pediatric patients was to *not* sell the pediatric model. For instance, Medtronic failed to train its Territory Managers regarding the pediatric pump. Relator does not recall receiving any training on the pediatric pump, nor any internal practice sessions on marketing it.

392. Part of Medtronic's training to its sales force included helping representatives be able to explain to healthcare providers the ins and outs of ordering specific products, prescribing and billing insurance. Consequently, Medtronic's sales representatives were intimately familiar with product names, descriptions, and billing information. However, Relator was never trained how to describe to a physician the pediatric pump, much less how to prescribe the pump.

393. Relator asked Medtronic DTA Michael Kim, an insurance specialist, what procedure a physician in his territory would follow to prescribe the pediatric pump. Mr. Kim, who at that time had been with Medtronic for approximately six years in several territories, replied that he did not know what that product was. This was remarkable

because Mr. Kim is the person who creates the LMN or CMN for the physician. By his response to Relator's question, Mr. Kim revealed that he was not even trained on what the pediatric pump was, let alone how to fill out the LMN or CMN for that product.

394. By way of further example, Relator is unaware of Medtronic's training guides for selling the integrated pump to pediatric providers ever addressing the pediatric model. Instead, he received materials such as the "Revel Yell." In March, 2010, Medtronic launched the Revel product and provided the "Revel Yell" selling points for pediatric patients and patients with Type 2 diabetes. Among the selling points was that the product's predictive alerts were good for pediatric patients—that predictive alerts "catch it early." The Revel Yell materials, which were distributed nationally by Sales Training Director Barbara Patterson and her team, made no mention of the *different* settings on the pediatric pump or that there is even a different pump approved for pediatric patients.

395. Further, Relator is unaware of any Medtronic sales representatives who used the pediatric model to demonstrate the benefits of an integrated pump at doctor's offices. Instead, the representatives routinely used the pump with the adult-default settings, even at pediatric provider's offices.

396. Consequently, Relator and other Territory Managers did not sell the pediatric pump to their pediatric providers. They were trained to reference that Medtronic's product had a "pediatric indication" but they did so in selling the adult pump.

397. One of Medtronic's most misleading sales tactics was in its competitive messaging. In speaking with healthcare providers regarding the DexCom Seven PLUS product, Medtronic directed its sales force to reference as a "safety issue" that

DexCom's product was contraindicated for pediatric patients. This was not true. Rather, like Medtronic's adult pump, it was not indicated for pediatric use. Similarly, in speaking with healthcare providers regarding Abbot's Navigator product, Relator and the sales force were directed to reference the same "pediatric contraindication" as a "safety issue."

398. Medtronic instructed its sales force to market against its competitors with these statements. In printed materials distributed at Medtronic's FY2011 national sales meeting, called the "fight club" packet, the following talking points were provided regarding the competitor products:

> **FACT: This product is not approved for use in patients less than 18 years of age.**
>
> Q1: What percentage of your patients are under the age of 18? How beneficial do you think CGM is for your patients under 18?
>
> Q2: What benefits do you think CGM provides for your patients of all ages?

(emphasis in original). Medtronic sales representatives were expected to deliver this message about its competitors to providers without telling them that Medtronic was marketing its unapproved pump in exactly the same way.

399. These statements misled providers, as Medtronic's adult pump was not approved for patients under 18, and there is no integrated pump approved for "all ages."

400. Thus, Medtronic's instructions to its sales force to make it a selling point that the REAL-Time product was the only product with a pediatric indication, even though they were selling the adult pump which did not have a pediatric indication, was highly misleading.

401. Medtronic also failed to properly identify that there was an integrated

pediatric pump on the market in such a way that doctors, pediatric patients and their parents would know they were receiving an off-label product.

402. By way of example, Medtronic routinely distributed an advertising packet to parents and doctors' offices entitled "Your Life. Your Way." Every office, clinic, or diabetes center who had been identified as a prescriber or a potential prescriber for pump therapy would have this packet in their office. The packet is replete with glossy pictures of children playing happily. It promises:

> When you add the [CGM] to your insulin pump …. You can see into the future. REAL-Time trend arrows help you avoid oncoming lows and highs before they happen. Stay in the game longer. CGM lets you personalize your insulin pump with high and low alarms so you get a heads up when it looks like you're going to be high or low.

403. The packet further summarizes "Medtronic has the first (and only) insulin pump with built-in CGM. You can see your blood glucose levels on your insulin pump every 5 minutes and it will warn you if you're about to go high or low." Conspicuously absent from the brochure, however, is an explanation that the pediatric pump and adult pump have different warning settings and any potential effect that might have on pediatric patients (see, e.g., paragraphs ¶¶ 412-414 below). In this packet, the only mention of the pediatric model pump is in the footnotes on the last page of the brochure, in tiny font, where it states:

> MiniMed Paradigm insulin pump therapy can be used with or without continuous glucose monitoring and is approved for patients of all ages who have Type 1 or Type 2 diabetes. The Medtronic REAL-Time Continuous Glucose Monitoring System is approved for all patients aged 7 years or older who have Type 1 or Type 2 diabetes. It is available separately in 2 models: one for age 7 to 17 and one for patients 18 years and older.

This footnote does not provide specific model numbers for the pediatric pump. Medtronic makes no effort to make it easy to differentiate the adult and pediatric pump.

Rather, the brochure is replete with references to being the “only” integrated CGM device. Consequently, most parents did not know whether their child received the pediatric model or not.[19]

404. Similar to above, Medtronic routinely distributed sales brochures to doctors regarding the benefits of using the "The world's ONE and ONLY integrated system” without educating the doctors as to the differences in indication between the pump models approved for adults and pediatric patients.

405. Another sales brochure extolled the benefits of “*REAL-Time Alerts* give patients peace of mind by helping them to minimize or avoid oncoming lows and highs. *NEW Predictive Alerts* can be set to warn your patients up to 30 minutes before their low or high glucose limits are reached. According to a recent internal study, the use of predictive alerts improved hypoglycemic event detection by 36% compared to the low glucose alert alone.” The only mention of the pediatric model was in very tiny print: “A version of the product specially designed for children is indicated for patients age 7-17.” However, it does not provide the different model numbers or an explanation of the difference in the adult and pediatric versions.

406. Further, Medtronic provided a worksheet entitled “CGM Initialization” as a guide to help doctors, Certified Diabetes Educators (CDEs), and Certified Pump

[19] Further, as in all of Medtronic’s main marketing brochures which are distributed to patients and left in doctors’ offices to be distributed, there is a very convenient pocket in the back of the brochure. Medtronic management instructs and encourages its sales representatives to load up the pocket with whatever material they believe will convince their customers to buy Medtronic’s diabetes devices, whether or not the material contains off-label messages or not. Further, the articles and homemade materials are often presented in a misleading fashion as if they are clinical data, as explained above. They often contain misleading statements and unapproved superiority claims about Medtronic’s products. For example, Relator reviewed homemade sales materials created by another sales representative in his District that mixed together two separate studies into one presentation and created the misleading impression that Medtronic’s insulin pump is far superior to the competing pumps.

Trainers (CPTs) know how to set the alert settings on the Medtronic Paradigm Real Time System when a pump patient starts using a sensor with the pump. The true business motive of this piece was to try to increase patient retention on the sensor by decreasing attrition due to frustrations with its alerts (high and low, but mostly low). Medtronic wanted to standardize the sensor training and the recommended alert settings in the hope that this would increase the retention rate.

407. This worksheet was dated 2010 and was distributed nationally and to practitioners that had all patient types. In Relator's region, for example, the worksheet was distributed to accounts that have pediatric patients including Dr. Kelly, in Medford, Oregon, Drs. Cuddihy, Monchamp and McCarthy in Bend, OR, Dr. Michaels in Salem, OR, and Jacque Corey, CPT and Dr. Jacobson in Eugene, OR.

408. This worksheet's author is Francine R. Kaufman, MD, Medtronic's Chief Medical Officer. She is a pediatric endocrinologist and past president of the American Diabetes Association as well as the Chair for many NIH studies. She also practices in Los Angeles at the Children's Hospital. She is a significant thought leader in pediatric diabetes. This was the type of worksheet that many CPTs and CDEs would have laminated in their office, unless they have memorized these settings.

409. While this was distributed to pediatric accounts, Medtronic failed to identify pediatric settings in the guidance. The settings it recommended for low glucose limits were not even possible in the pediatric model. However, it was clear, given its distribution and its excluded class, that Medtronic intended its application for pediatric patients. The settings only excluded pregnancy, "where the urgency of tight control and more aggressive target ranges need to be considered." Pediatric patients were <u>not</u>

excluded from the recommendations that followed.

410. Under the heading “Glucose Limits,” and sub-headings “Considerations When Setting Low Glucose Alerts” and “Managing Low Glucose Limits,” the recommendations state: “Setting Low Glucose Limits at 70 mg/dL will help to detect lows, but still limit frequency of alerts.” This recommended setting is not possible on the pediatric pump (which cannot be set at lower than 90 mg/dL).

411. Given that these recommendations do not exclude pediatric patients, it is clear that Medtronic management assumed that the pediatric patients would be using the adult pump. The difference between 70 and 90 mg/dL is enormous because patients try to keep their blood sugar between 80 and 120 mg/dL. A blood sugar of 70 mg/dL is already considered to be a very low blood sugar (hypoglycemia) which can cause loss of consciousness or death if it persists. Because the sensor is on average +/- 20% from the real value, setting the alert at 70 mg/dL means that Medtronic is recommending that the patient not be alerted until what could very easily be a blood sugar of 56 mg/dL. Medtronic recommends setting the low glucose alert at 70 so that patients won’t be annoyed by frequent alerts; but the FDA required that the pediatric model be set no lower than 90 to prevent episodes of hypoglycemia.

412. Medtronic was fully aware of the dangers in setting the sensors too low in children. Buried in its User Guide for the Paradigm Real Time Revel (2009 ed.), on page 231, the Guide discusses “Low and High alerts in children and adolescents.” This section discusses a clinical study that evaluated the accuracy of the sensor component of the integrated system when used by children and adolescents. The Guide provides the following summary of the study:

> The Low Glucose Alert was evaluated for its ability to detect glucose levels at 70 mg/dL (3.9 mmol/L), or below, using the blood glucose meter. As a reference, with the Low Glucose Alert set at 70 mg/dL (3.8mmol/L), 24% (59/244) of low glucose events were detected by the Guardian RT. Better detection of low blood glucose can be obtained by setting the Low Glucose Alert level higher. For example, setting the Low Glucose Alert at 90 mg/dL (5.0 mmol/L), instead of 70 mg/dL (3.9 mmol/L), increases the ability to detect low blood glucose levels from 24% to 70%

In other words, only 24% of the time did the device work and alert the patients that they were having a low glucose episode. This means that, most of the time, the device *never* alerted when the patient could have had low blood glucose readings of 50, 40, 30 . . . . or passed out in a coma. This statistic would be shocking to a parent or HCP if they were aware that Medtronic was selling pediatric patients an adult pump that can have the low blood glucose alert set at 70 mg/dL, as opposed to the minimum setting of 90 mg/dL on the FDA-approved pediatric pump.

413. As noted above, the same data shows that if the low glucose alert is set at 90 mg/dL, as required in the pediatric model pump, the device detects low blood glucose episodes a much more acceptable 70% of the time. (This represents a 180% improvement in hypoglycemia detection compared to the 24% detection rate when the alert is set at 70 mg/dL.) Thus, the device is reasonably reliable in hypoglycemia detection at 90 mg/dL, which is why the FDA approved the pediatric pump as safe and effective in this population. By providing pediatric patients with the adult pump, Medtronic is circumventing the FDA's safety requirements in order to reduce the number of annoyance alerts, but at the cost of reducing the device's ability to alert the patient prior to a hypoglycemic event. Yet, it is precisely because the device can alert patients prior to a hypoglycemic event that patients use the device, doctors prescribe it, and insurers reimburse it.

414. In contrast to pediatric patients, the clinical study data for adults is better. When the low glucose alert is set at 90 mg/dL for adult patients, the low glucose episode detection rate is 82%, and at 70 mg/dL the detection rate is 49%. This makes clear why the FDA singled out children as requiring a separate device with more conservative settings. Simply put, the device is less effective in alerting children of low blood glucose episodes than it is adults. When Medtronic promoted the adult pump off-label to pediatric patients, it was disregarding clinical data, reported in its own User Guide, showing that the alert settings in the adult device present a clear and known danger to pediatric patients. The sole motivation for Medtronic's conduct was increased profits, since Medtronic knew that the low blood glucose alerts in the pediatric model would be an annoyance and lead to increased attrition among users.

415. The company's message to parents was that if their child was placed on the Paradigm Real Time system, they could rest assured at night knowing that the sensor will alert the parent or the child if the child's blood glucose drops below safe levels in the middle of the night. Most parents prior to using the device would have to wake up several times a night and take their child's blood sugar in order to guard against an extreme low in the middle of the night that could be potentially life threatening. Medtronic instructed its sales representatives to tell parents that once their child was put on the Paradigm Real Time system, they could sleep throughout the night without having to get up and check their child several times. Parents were told to put a baby monitor in the child's room and one in their room. If an alert went off, it would wake them up. No more sleepless nights. No more nights of constantly checking and of worrying. However, this was highly misleading, as with Medtronic's alert settings on

the adult pump, a parent will only be alerted in 1 of 4 hypoglycemic events.

416. All of the above-described methods are ways in which Medtronic falsely represented to prescribers the pumps as effective and safe for use in pediatric patients.

2. Medtronic's Scheme Resulted in Materially False Claims.

417. As alleged more specifically in Section VI infra, Medtronic knew that its practices resulted in claims to government healthcare programs, and that those claims were subject to the conditions of payment of those programs.

418. As a condition of payment, only reasonable and necessary items and services are covered by government healthcare programs.

419. An item or service is not "reasonable and necessary" if it is not safe and effective.

420. Medtronic is aware that its adult integrated pump is not approved for use by pediatric patients and that its use is not supported as safe and effective by any major compendia, authoritative literature, or accepted standards of medical practice.

421. Unlabeled uses of devices which are not supported by evidence of safety and effectiveness are not reasonable and necessary.

422. Medtronic's false representations and omissions regarding the safety and effectiveness of the use of its adult integrated pump by pediatric patients would have a natural tendency to influence the Government's decision to pay the resulting claims.

423. Every claim submitted to the government (1) for a Medtronic insulin adult pump or (2) for a glucose sensor sold off-label to a pediatric patient as a result of Medtronic's off-label promotional practices described herein constitutes a false and fraudulent claim in violation of the federal and state False Claims Acts.

424. Representative examples of government healthcare claims resulting from this scheme include:

Pt. Initials	Provider Name	Location	Payor
AT	McCarthy	Bend, OR	Medicaid
AS	Bassett	Salem, OR	Medicaid
CR	Storriolo, Cosmo	Corvallis, OR	Medicaid
DD	Miller	Unk.	Medicaid
KA	McCarthy	Unk.	Medicare
LP	Pardini	Eugene, OR	Medicaid
ML	Pungan	Unk.	Medicare
RC	Chamberlin, Thomas	Unk.	Medicare
SM	McCarthy	Redmond, OR	Medicaid

425. Representative examples of physicians who were targeted by Medtronic for adult integrated pump orders for their pediatric patients, and who were in fact induced to order those pumps for their pediatric patients, include:

i. Dr. Rodney Michaels, Salem, Oregon

ii. Dr. Travis Monchamp, Bend and Redmond, Oregon

iii. Dr. Alan Kelly, Medford Oregon

iv. Dr. Mary Carroll, Bend, Oregon (children that are 14-17 only)

v. Dr. Kirk Jacobson, Eugene, Oregon

vii. Dr. Patrick McCarthy, Bend, Oregon

viii. Dr. Rajesh Ravuri, Coos Bay, Oregon

426. By way of further example, in January or February 2011, Dr. Rajesh Ravuri informed Relator that he intended to put 30 children on the pump.

427. These fraudulent schemes have been occurring since at least 2006 and are on-going.

V. Medtronic Causes the Submission of False Claims for Unnecessary Orders for Insulin Pump Upgrades and Replacements.

428. Sales of replacement insulin pumps, including upgrades, constitute the largest share of revenue for Medtronic's Diabetes Division. Many of these sales are the result of a fraudulent scheme whereby Medtronic solicits patients to order insulin pump replacements or upgrades before they are needed and falsifies the justification submitted to insurers in order to obtain reimbursement.

429. By way of background, most Medtronic insulin pumps come with a four year manufacturers' warranty for non-Medicare patients and a five year warranty for Medicare patients. If a pump experiences a malfunction that impairs normal use of the equipment during the warranty period, it is Medtronic's responsibility to replace it at the company's expense. If a pump malfunctions after this period, the patient typically can obtain reimbursement for a new pump through his or her insurance company. A replacement unit is also reimbursable by the insurance company if there is a medically necessary justification for a new pump.

430. Government reimbursement is specifically prohibited if Medtronic knowingly submits a claim generated pursuant to an unsolicited telephone call to in an individual, unless it has the written permission of the patient or is following up on a contact for the furnishing of another covered item made within the preceding 15 year period. 42.U.S.C. § 1395m(a)(17)(B). Medtronic's solicitations fall within the prohibitions of § 1395m.

A. Medtronic Persuades Patients to Unnecessarily Replace Insulin Pumps.

431. Medtronic tracks all of its pump sales in a database. The database includes the patient's name, contact information, and date of shipment. Medtronic

provides each Territory Manager with a list of the patients located in his or her Territory. The Territory Managers calculate the out of warranty (OOW) date by adding four years (or five years, in the case of Medicare patients) to the shipment date.

432. Medtronic employees are directed to obtain patient identifying information from physicians and then use that HIPAA-protected patient information to contact patients regarding their products and for other marketing purposes. Medtronic even provides its sales representatives with a template letter that they can print on Medtronic stationary that states very authoritatively that Medtronic is a “covered entity” under HIPAA, even though it omits that HIPAA does not permit a “covered entity” to use protected patient information for marketing purposes.

433. Medtronic imposes a very high quota on Territory Managers for sales of upgraded or replacement pumps. For example, Relator’s last quota before he was terminated required that he sell $978,142.00 worth of replacement pumps in the current year. That amount is more than half of the total new pump sales in Relator’s territory in any given year. As a practical matter that means that Medtronic requires that its sales representatives solicit and convince a substantial portion of the patients to upgrade. If they do not meet the quota, the sales representatives are subject to termination.

434. In order to meet this quota, it is standard practice for Territory Managers, or DTCs in the Medtronic call center who assist the Territory Managers, to make unsolicited telephone contact with the pump wearers shortly after the pump warranty expires for the purpose of convincing the wearers (i) that they need a replacement pump and (ii) that they can obtain insurance reimbursement for the replacement.

435. It is also standard practice for Territory Managers, or DTCs to make

unsolicited telephone contact with the pump wearers prior to the pump warranty expiration in order to convince them that need an upgrade.

436. Medtronic further encourages the Territory Managers and DTCs to use deceptive telephone interview techniques in order to convince the OOW pump wearers to claim that their current pump has malfunctioned, which will justify insurance coverage for a replacement model, or for in-warranty pump wearers to claim that they need an upgrade.

B. Medtronic Causes False Claims of Pump Malfunctions to be Submitted.

437. In the unsolicited calls with the OOW pump wearers, the Medtronic representatives are armed with a list of questions about possible issues with a pump, including features that do not affect normal pump use (such as buttons worn down, scratches on the screen of the monitor, or reduced battery life). If the pump wearer provides anything resembling an affirmative answer, such as “sometimes” or “I think so,” the representative fills out the necessary insurance paperwork stating, falsely, that the equipment has malfunctioned and that a replacement unit is needed.

438. OOW pump wearers are usually more than happy to go along with this scam and sign the insurance paperwork, since it means they can get a new pump with a new warranty, covered by their insurance. Even if there is a co-pay, it is usually worth it to the patient to have a new model that is covered by a full warranty. And if the co-pay is a sticking point, Medtronic takes care of that by offering financial aid and/or a trade-in credit on the patient’s old pump. Since every sale represents thousands of dollars in profit for Medtronic, the company is quite willing to give up $1,000 in financial aid and trade-in credit to make a sale. Simply put, Medtronic makes sure that there is no

reason not to upgrade.

439. In Relator's sales territory, two Oregon Health Plans (Medicaid) – Cascade Comprehensive Care and Marion Polk Community – stopped approving Medtronic insulin pumps for coverage because of these practices. Relator had a number of communications with administrators of these health plans to try to convince them to cover Medtronic's insulin pump. The administrators told Relator that they did not want to do business with Medtronic because they knew from their members that Medtronic was calling up OOW pump wearers shortly after warranty expiry and causing them to make up defects in order to get insurance reimbursement for the upgrade. Although these health plans caught on to the scheme and stopped reimbursing Medtronic pumps, to Relator's knowledge Medicare has never caught on to the fraudulent scheme.

440. Prior to November 2009, the standard practice at Medtronic was for Territory Managers and DTCs to make unsolicited telephone calls to OOW pump wearers immediately after the warranty expired, i.e. the same day or at most a day or two after the expiration. In November 2009, Medtronic management issued a new policy that prohibited calling commercial and Medicaid patients until 4 years 4 months after the shipment date; Medicare patients until 5 years after the shipment date. Medtronic's policy did not prohibit unsolicited telephone contact, however, and also stated that the policy could be temporarily or permanently adjusted at any time at the discretion of Sales Leadership based on business conditions and/or need.

441. The fact that management issued a formal policy on this shows that the practice of contacting OOW patients to sell them replacement pumps was

institutionalized, and management's only concern was how quickly after warranty expiration the OOW patients could be contacted.

442. It further explained what the OOW Policy meant to various categories of employees, including:

> Field Sales: Support HCP driven OOW patients by collecting necessary backup and sending these leads to your DTC to contact. You do not need to identify or send to your DTCs any other OOW leads who meet the terms of the policy, as the DTC team is made aware of these patients through internal processes on an ongoing basis. …
>
> DTC: Contact all patient leads you receive who are eligeible [sic.] per the OOW Policy …

443. On August 6, 2010, District Manager Mike Ware sent an email to his team reminding them to follow the above-described OWW Policy. However, he also identified two "opportunities that we can contact OWW prior to timeline established by Medtronic." First, "OOW patients may be called earlier than the policy dictates only at the request of an HCP." Second, "Competitive Upgrades are exempt from this policy." However, these exceptions are nowhere stated in the rule prohibiting Medicare claims based on unsolicited telephone calls.

444. The fraudulent practices alleged herein became so rampant and widespread within the company that on January 31, 2011, Mike Gill, Vice President of Sales, sent a cautionary email to the entire sales force and DTC/ DTA teams. The email began by explaining

> Recently, we have received complaints from payers (and patients) that some upgrades for out-of-warranty pumps were unnecessary, including allegations of fabricated malfunctions.

Mr. Gill's email goes on to explain that an internal review of "call records, notes in the system, and summaries in CMNs [Certificates of Medical Necessity]," revealed that

"some upgrades were not supportable. In these cases, the actual pump malfunctions were exaggerated or assumed, and did not accurately represent the information given by patients." (Emphasis in original.)

445. Mr. Gill continued with a frank warning: "any upgrades that are based on fabrication, exaggeration, or a disregard for what the patient actually stated, cannot be tolerated." Such a warning, from the Vice President of Sales, would not have been necessary if the practice had not become widespread.

446. Mr. Gill's email ends with a series of "instructions" to the sales force of what to do and what not to do. This list of "don'ts" is a road map of exactly what Medtronic representatives had been doing for the entire time Relator worked for the company:

> When summarizing information from patients about potential pump problems, make sure your notes are entirely accurate and reasonable. Do not guess, assume problems, jump to conclusion or exaggerate in any way.
>
> To support an upgrade, you must have enough information to show a legitimate malfunction exists. For example, a patient simply answering "yes", "sometimes", or "I think so", to questions about bad alarms, buttons, battery, screen, or any other pump issue, is NOT enough. Instead of moving on to the next question. you must ask them to explain the seriousness of the problem (for example how often,. how bad the problem actually is, whether it prevents normal pump use, etc.). In other words, the patient's statements must support a malfunction that prevents or inhibits normal pump operation, such that the malfunction is or may be a safety risk to the patient.
>
> If a malfunction exists but the pump is still in warranty, you must refer the patient to the 24- hour Helpline for assistance. Purposely waiting or creating delay until the warranty period expires is unacceptable and will not be tolerated.

(Emphasis in original.)

447. These "instructions" about what not to do summarize the practices that

had become routine by January 2011. Moreover, the instructions continued to emphasize it was acceptable to make unsolicited phone calls, stating in the same email: "As you know, pump upgrades for malfunction (or clinical) reasons are entirely acceptable, and we strongly encourage your continued outreach efforts to help patients in these cases."

448. If a patient does not believe that they need a new/upgraded pump, Medtronic tries to scare the patients into thinking that if their OOW pump breaks they will have to go onto insulin shots for several weeks or longer until their new pump is approved. In truth, Medtronic will provide patients in that situation with a free "loaner pump." Yet Medtronic representatives are trained not to mention that to the patients so that the scare tactics will work and the patients will order a replacement pump with a new warranty even if their present pump is in perfectly good condition.

449. Relator is informed and believes that the majority of all claims for insurance reimbursement for OOW replacement insulin pumps were the result of the above fraudulent practices. Each such claim submitted to the government is a false and fraudulent claim in violation of the federal and state false claims acts.

450. These fraudulent schemes have been occurring since at least 2004 and are on-going.

C. Medtronic Causes False Letters of Necessity to be Submitted.

451. Orders for upgrade pumps also result from these unsolicited contacts with patients, made to pup wearers both in and out of warranty. In addition to falsifying reasons for pump malfunction, Medtronic sales representatives are directed to falsify the medical necessity for upgrade pumps.

452. Medtronic routinely prepares Letters of Medical Necessity ("LMN") for physicians to sign justifying the medical necessity for a pump upgrade. In the case of the upgrade from pump model no. 508 or 511 to model no. 512 and 515, virtually every LMN prepared by Medtronic and signed by physicians provided a fabricated medical justification for the upgrade. (All references to model numbers herein include the equivalent model in larger size. For example, reference to model 515 includes the 715, which is the same model with a larger reservoir.)

453. One difference between the 508 or 511 and 512 and 515 models is that the former delivered insulin in 0.10 units and the latter had the ability to deliver insulin in .05 units. Medtronic prepared an LMN for physicians that stated that because of a change in the patient's medical condition, the patient would benefit from the .05 unit delivery feature of the 512 pump, even though this was a fabricated justification and there was no evidence that it was true. Medtronic's template LMN for Medicare reimbursement stated:

> [Patient's Name] is a patient of mine who has diabetes and who has been on insulin for the last XX years. She has always had somewhat erratic blood sugars that were relatively controlled with her 508 pump, which she is currently using. Recently, the patient has been experiencing severe erratic blood sugars which we are having difficulties controlling with the current 508 pump. The .05 unit delivery feature available on the 512, 712 paradigm pumps will assist in providing her precise insulin dosing with controlled steady delivery. This feature is not available in her current 508 insulin pump. The .05 unit delivery feature will assist in giving her tighter control of her blood sugars. For the reasons stated above, I am prescribing the MiniMed 512 Insulin Pump for [Patient's Name].

454. Medtronic found that the only way to get Medicare approval for the upgrade from the 508 or 511 to the 512 or 515 based on change in medical condition was by using this LMN verbatim. The letter came from the Medtronic Medicare department and was circulated to the sales force nationwide. This pre-populated letter

was also faxed directly to a physician's office for signature.

455. If doctors prepared their own letter and honestly described the patient's condition and reasons for upgrading, the upgrades were never approved. Thus, Medtronic prepared the same LMN for every patient for whom an upgrade from the 508 or 511 to the 512 or 515 was sought, and most physicians signed it. This took place in the period from 2003 to 2008.

456. The justification in the Medtronic-prepared LMN was a sham. There was no evidence that these patients would benefit by the .05 unit delivery feature available on the 512 or 515. Relator knew of no one at Medtronic that actually believed that the .05 unit delivery feature had a significant therapeutic effect. In fact, Medtronic spent considerable resources in trying to persuade doctors that the ability to dose at very small unit levels did not matter, since competitor Animas Corporation's insulin pump can dose at .025 units. Medtronic claimed that this made no difference.

457. This strategy continued when it came time for the 512 pumps to be upgraded. In the case of upgrades to the 515 and 522 models, Medtronic's template LMN focused on the new model having an adjustable active insulin curve in the bolus calculator. Medtronic's template LMN falsely claimed that this new feature was medically necessary for the patient, in order to get approval for upgrades from the 512 model to the 515 and 522. This justification was essential because patients upgrading from a 512 could no longer simply rely on the .05 basal rate that was utilized in prior narrative LMNs. In the case of the 512, the upgrade needed to be supported by the adjustable active insulin curve feature. This feature was not supportable by any clinical evidence. Nevertheless, Medtronic led physicians to believe that it was an important

feature and prepared LMNs for their signature stating that the feature was medically necessary.

458. Relator is informed and believes that the majority of upgrades from the 508 or 511 to the 512 or 515 insulin pump, as well as upgrades from the 508, 511, and 512 to the 515 and 522 insulin pump, were reimbursed by government insurers based upon false and misleading LMNs prepared by Medtronic. As such, each claim for reimbursement for these insulin pumps violated the state and federal False Claims Acts.

459. Medtronic representatives, including Relator, spent a substantial amount of time creating justifications, real or contrived, to obtain reimbursement, since most patients will not purchase a pump unless it is covered by Medicare/Medicaid or a private insurer. In one instance, Dr. Phillip Taggart of the Oregon Medical Group was attempting to obtain an upgraded insulin pump for one of his Medicare patients, “AS” but had been unsuccessful. Relator obtained Dr. Taggart’s letter to HHS requesting a new pump and provided it to Medtronic’s Medicare Approval Dept. which responded by pointing out missing information and summarizing necessary revisions. Medtronic’s corporate office also provided Dr. Taggart with a sample letter to follow. In addition, Relator corresponded with Dr. Taggart’s Medical Assistant, Marcia, outlining the reasons why coverage for the insulin pump had been denied, “I want to make sure that I make it clear that the true reason for not getting an insulin pump is that there was no recent change in medical condition noted in the letter from Dr. Taggart.” Ultimately, Dr. Taggart made changes suggested by Medtronic and the in-warranty upgrade was approved and paid for by Medicare.

460. Another example of medical necessity letter drafted by Medtronic for a

physician is a draft prepared by Relator for Dr. John Nelson on behalf of patient "TL" on October 19, 2010. Using the same scheme as described above, to justify an upgrade to the new model, the focus was placed on the difference between the old Model 512 and the new Model 523. The letter focused on the former model being capable of delivering insulin in 0.05 units, while new model is capable of delivering insulin in 0.025 increments. Upon information and belief, this was an in-warranty upgrade for a Medicare patient.

461. These fraudulent schemes have been occurring since at least 2004 and are on-going.

D. Medtronic Avoids Covering Warranty Claims in Order to Push Costs Onto Government and Private Insurers.

462. If an individual's pump is broken or malfunctioning, they will telephone Medtronic's 24 hour helpline, in an attempt to gain assistance. It is important to note that inbound calls to Medtronic regarding broken pumps are handled by a different team than the outbound solicitation calls.

463. In instances where a patient calls up the Medtronic helpline with a legitimate malfunction and the unit is still under warranty but close to the expiration of the warranty, Medtronic representatives would often purposely wait or create delay until the warranty period expires, in order to try to shift the cost of replacement from the company to the patient's insurance company.

464. Medtronic engaged in a variety of practices to dissuade customers from making a warranty claim within the warranty period. Medtronic does not want to honor legitimate warranty claims for at least two reasons. First, Medtronic bears the considerable expense of replacing the unit, including shipping the new unit and return of

the old. Second, even though the new unit does not come with a new warranty (the original warranty period applies), the holder of the new unit is less receptive to the standard OOW call shortly after warranty expiration since the patient has just received a new unit and has consistently heard from Medtronic that its pumps should last at least four years.

465. Medtronic made it very difficult for pump wearers who were entitled to an in-warranty replacement to actually receive the replacement. When Relator visited the 24 telephone helpline office in the Diabetes Division's corporate headquarters, he saw only three people working there. That is miniscule in comparison to the hundreds of thousands of people using Medtronic devices. The waiting time on calls was often so long that many pump wearers would give up. Territory Managers have a secret extension that moves them to the front of the call line in case they are at a doctor's office or with a patient. This creates the impression for doctors and patients that hold times are not so long and that stories about the long hold times are exaggerated or unfounded.

466. The patients who are persistent enough to finally get through and speak to the helpline staff are put through a protocol designed to deter them from making an in warranty claim. They are told that the problem with their pump is probably caused by something other than the pump itself – either a problem with the infusion set they are using (an inexpensive supply), a problem with their insertion method, or a problem caused by the patient. Often the helpline staff will tell the patient that they will be sent a new infusion set to try. If the patient calls back later after trying the new infusion set, the stonewalling protocol begins again. Many patients give up and use their broken pump.

467. By deterring patients from making legitimate in warranty claims for a replacement unit, Medtronic shifts the cost of replacing the pumps to government and private insurers. Once the pump is out of warranty, Medtronic quickly moves in and assists the patient to order a new replacement pump, at the insurers' expense. Invariably, the OOW malfunction will be one that occurred while the pump was still in warranty. (This was particularly obvious when Medtronic made the OOW call within a day of the warranty expiration.) These practices cost government and private insurers tens and possibly hundreds of millions of dollars.

E. Medtronic's Scheme Resulted in Materially False Claims.

468. As alleged more specifically in Section VI below, Medtronic knew that its practices resulted in claims to government healthcare programs, and that those claims were subject to the conditions of payment of those programs.

469. Government healthcare programs restrict coverage of replacement pumps to those made necessary by the lapse of the reasonable useful life of the equipment or due to loss or damage.

470. Government healthcare programs will not pay claims resulting from improper solicitations of patients by suppliers. Medtronic's actions to cause the submission of claims in violation of the express prohibitions of 42 U.S.C. § 1395m would have a natural tendency to influence the Government's decision to pay the resulting claims.

471. Government healthcare programs will only pay for upgraded pumps that are reasonable and necessary. Upgraded pumps that exceed a patient's medical needs are not reasonable and necessary.

472. Medtronic's misrepresentations regarding the need for upgraded pumps would have a natural tendency to influence the Government's decision to pay the resulting claims.

473. Each claim for reimbursement caused by Medtronic's fraudulent conduct constitutes a false and fraudulent claim in violation of the federal and state false claims acts.

474. Representative examples of claims resulting from Medtronic's material representations regarding the eligibility of the patient for an upgraded or replacement pump include:

Pt. Initials	Approximate Date of Service	Provider Name	Location	Payor	Order
DL	unk.	Theen	Medford, OR	Medicaid	Upgrade
EP	2/17/2011	Carroll, Mary	Bend, OR	Medicare	Out of Warranty
EH	unk.	Cirullo, Ronald, M.D.	unk.	Medicare	Upgrade
FW	unk.	Cirullo, Ronald, M.D.	unk.	Medicare	Upgrade
JE	unk.	Abacan	Roseburg, OR	Medicare	Upgrade
LS	1/17/2011	Bassett, Martin L., M.D.	Salem, OR	Medicare	Out of Warranty
LH	unk.	Gallen, John	unk.	Medicare	Upgrade
MG	unk.	Bradley	Roseburg, OR	Medicare & VA	Upgrade
ND	8/8/2005	Carroll; Harris, Michael	Bend, OR	NRECA & Medicare	Upgrade
RW	2/25/2011	Bassett, Martin	unk.	Medicare/Trans America	Upgrade
SM	2/25/2011	Bailey, Georgy	unk.	Care-Oregon-Medicaid	Upgrade

SG	5/15/2006	Farmer	Eugene, OR	Medicare	Upgrade
SH		Goldstein	Bend, OR	Medicare	Upgrade
TL	10/18/2010	Nelson, John	Eugene, OR	Medicare	Out of Warranty
TS	10/19/2010	Eddy	unk.	Medicare	Out of warranty
CF	5/10/2011	Hao	Corvallis, OR	Medicare	In-warranty
RS	2/8/2006	Galen, John	Medford, OR	Medicare	In warranty
EJ	unk.	Carroll, Mary	Bend, OR	Medicare	In warranty
KB	9/21/2005	Taggart, Phillip	Northridge, CA	Medicare	In warranty
LG	3/22/2005	Britsch, Barbara	unk.	Medicare	In warranty
PD	5/26/2005	unk.	unk.	Medicare	In warranty
JV	7/7/2005	Gentry, Robert	unk.	Medicare	In warranty
KQ	5/26/2005	Michaels, Rodney	unk.	Medicare	In warranty
JH	5/27/2005	Theen, James	unk.	Medicare	In warranty
LC	4/14/2005	McCarthy, Patrick	unk.	Medicare	In warranty
AL	8/2/2005	Chamberlain, Thomas	unk.	Medicare	In warranty
JW	6/8/2005	Britsch, Barbara	unk.	Medicare	In warranty

475. Representative examples of providers who relied on Medtronic's material misrepresentations relating to the eligibility of patients for an upgraded or replacement pump include:

- Dr. John Gallen, Medford, OR
- Dr. Krishnamurthy, Salem, OR
- John Nelson, Eugene, OR

- Dr. Radhakrishnan, Salem, OR
- Dr. Mary Carroll, Bend, Or
- Dr. Pardini, Eugene, Or
- Dr. Kirk Jacobson, Eugene, OR
- Dr. James Theen, Medford, or
- Dr. Richard Eddy, Medford, OR

476. These fraudulent schemes have been occurring since at least 2004 and are on-going.

VI. Medtronic Knew That Their Schemes Resulted in Claims to Government Healthcare Programs.

477. Defendants knew that the reasonable and foreseeable consequence of their schemes was the submission of claims to government healthcare programs.

478. In fact, Defendants affirmatively state that their ability to sell Medtronic products is *dependent on* reimbursement from government programs:

> Even though a new medical device may have been cleared for commercial distribution, we may find limited demand for the device until reimbursement approval has been obtained from governmental and private third-party payers.

Medtronic 2012 Annual Report at p.15.

479. Defendants also knew that government healthcare laws applied when seeking reimbursement under Medicare, Medicaid and other government funded health care programs:

> Federal health care laws apply when we or customers submit claims for items or services that are reimbursed under Medicare, Medicaid, or other federally-funded health care programs. The principal federal laws include: (1) the False Claims Act which prohibits the submission of false or otherwise improper claims for payment to a federally-funded health care program; (2) the Anti-Kickback Statute which prohibits offers to pay or receive remuneration of any kind for the purpose of inducing or rewarding referrals of

> items or services reimbursable by a Federal health care program; (3) the Stark law which prohibits physicians from referring Medicare or Medicaid patients to a provider that bills these programs for the provision of certain 15 designated health services if the physician (or a member of the physician's immediate family) has a Financial relationship with that provider; and (4) health care fraud statutes that prohibit false statements and improper claims to any third-party payer. There are often similar state false claims, anti-kickback, and anti-self-referral and insurance laws that apply to state-funded Medicaid and other health care programs and private third party payers.

Medtronic 2012 Annual Report at pp. 15-16; *see id.* at 19 (U.S. federal government health care laws apply when we submit a claim on behalf of a U.S. federal health care program beneficiary, or when a customer submits a claim for an item or service that is reimbursed under a U.S. federal government-funded health care program, such as Medicare or Medicaid).

480. Thus, Defendants not only knew, but intended, for claims for items and services relating to its diabetic products to be paid by government healthcare programs

481. As identified further below, Defendants' records are replete with examples of this knowledge and intention. Defendants provided consulting services to providers regarding government healthcare reimbursement, tracked the amounts of government reimbursement for their diabetic products, and even marketed their products to health care providers utilizing economic presentations that illustrated potential revenue to the providers from insurers, including government funded healthcare programs (one of the most significant consumers for diabetic products).

482. Defendants well knew and Relator personally observed that Defendants' practices impacted government healthcare programs, and that government healthcare beneficiaries were a significant target for Medtronic's business.

A. Medtronic Collected Information on and Tracked Government Reimbursement of Targeted Healthcare Providers.

483. Knowledge of a healthcare provider's government reimbursement/payor mix was extremely important to Medtronic. As indicated below, Medtronic used this information to target practices for its illegal incentives and promotions. Consequently, Medtronic employed a variety of methods to collect and track this information.

484. By way of example, Medtronic compiled "Account Profile Sheets" for its targeted providers, which among other things, tracks a practice's Medicare versus private payor mix and calculates the "Economics", to include reimbursement numbers for the Top 5 Payors for the practice.

485. For instance, Medtronic's Account Profile of the Adventist Diabetes Center revealed that Medicare patients comprised 30% of the practice; the Account Profile of The Dr. Bassett Clinic in Salem, Oregon, revealed a 40% Medicare and 15% Medicaid patient population; the Account Profile of Peace Health of Eugene, Oregon, revealed a 35% Medicare and 20% Medicaid population; and its profile of Institute of Diabetes and Endocrinology revealed 60% of its patient received Medicare coverage and 10% were covered by Medicaid. Thus, Medtronic is well aware of the public and private mix of its provider targets, and the fact that government healthcare programs is a prominent payor for the patients of its provider targets.

486. Further, sales representatives regularly collected Explanation of Benefits ("EOBs") information on patients, including Medicare and Medicaid patients, as well as Medicare allowable percentages per plan from physicians and/or their office managers. By way of example, Medtronic Field Sales Training Manager Erin Lynch created a presentation entitled "iPro Positioning for success." In it, she instructed sales

representatives to conduct a thirty minute once per month office manager consult in which the representative engaged in “EOB Collection/Medicare allowable percentage per plan.”

487. Medtronic also compiled the EOB information into an “EOB Rollup,” in order to track trends in reimbursement amounts. Specifically, sales representatives in each region would collect EOBs from their accounts and submit or “roll them up” to their District Managers who would track them and in turn “roll them up” to the Regional Managers or managed care providers.

488. Medtronic’s collection efforts included providers of the Veterans Administration. For instance, in a special Veterans Administration Issue of Medtronic’s newsletter, *Channel Sales Chronicle*, it lists the “Top Performing Veterans Administration Medical Centers” (VAMCs) for 2010 based on purchases of Medtronic Insulin Pumps.

489. Medtronic also had its sales representatives collect information directly from office managers and practice administrators. For instance, in an Economic Outcomes Workshop entitled “Play Big”, Medtronic provided its employees “case studies” showing how to use economic outcomes, including reimbursement information, to gain further business from practices. These case studies collected the Medicare reimbursement information collected from staff of the West Endocrinology Group in Los Angeles, California (20% Medicare) and of Dr. Howard Edelman’s Endocrinology practice in Portland, Maine (30% Medicare). It then instructed on how to further develop business by collecting reimbursement information for each study:

> Gain commitment from [doctor] to work with [office manager] once a month to track reimbursement to ensure positive economic outcomes

> within the practice. Take a few minutes to show him the reimbursement tracker. Gain his commitment to review this with him at a monthly touch point meeting to review process, identify areas of concern, and share early success.

490. By way of further example, in its National Meeting Sales Force Success Kit for FY09, Medtronic trained its sales representatives to ask about current reimbursement protocol, even advising them to use the term "appropriate reimbursement" rather than "revenue stream." It further instructed them to "Obtain Payor Mix information" and to "Meet with the Office Manager to identify payor issues."

491. The variety of methods described above can leave no doubt that Medtronic knew their schemes would result in the submission of claims to government healthcare programs.

B. Government Reimbursement was part of Medtronic's Sales Pitch.

492. Medtronic's knowledge of government healthcare reimbursement was not academic—Medtronic used this information to target practices for its illegal incentives and promotions. Medtronic utilized the data to pitch its products--showing practices the specific ways they could profit.

493. By way of example, Medtronic trained its sales representatives to use Economic Models in presentations to show how much money the practice would generate from ordering devices from Medtronic. Specifically, Medtronic created the "Insulin Pump Therapy and CMG Reimbursement Tool" that captured the percentage of each practice's Medicare patients, and calculated the estimated reimbursement that would result from GCM, pump, and training orders for those patients.

494. Defendants' sales representatives were explicitly told to make economic presentations using the "Insulin Pump Therapy and CMG Reimbursement Tool" to

capture information from physician's offices regarding patient populations largely consisting of Medicare and Medicaid beneficiaries. By way of example, Relator was instructed, and did, use this tool in a presentation in June 2009 to Dr. John Matz. In it, the presentation calculates the number of CGM patients per week at Medicare reimbursement rates and provides the physician with a total estimated net reimbursement per Medicare patient ($238) and total estimated Medicare net CGM reimbursement per year ($171,238).

495. In furtherance of aiding its representatives to make successful presentations, Medtronic provides "Economic Skills" training to its sales representatives on how to determine target practices' economic return for Medicare patients. In Medtronic's Economic Skills training, sales representative are instructed on how to determine, inter alia, the net reimbursement from Medicare that iPro evaluations would bring into the practice. One such skill practice used the example of Howard Edelman in Portland Maine.

496. Medtronic also instructs its representatives to use the Medicare National Average for reimbursement to persuade physicians to move their pump patients to Medtronic's CareLink sensor based units to increase physician revenue. Additionally, sales representatives are required to use either a Medical Economics article or Medtronic's CGM Billing and Reimbursement Guide to demonstrate the ability to bill for data interpretation.

497. Medtronic's knowledge of and focus on government healthcare reimbursement is visible in its presentations at National Sales Meetings and by various managers who repeatedly and routinely utilize reimbursement data to focus on

"revenue" opportunities.

498. By way of example, in a PowerPoint titled "Introducing CGMS iPro with Mach 5," presented at Medtronic's 2008 National Sales Meeting, representatives are trained to "Educate on Reimbursement", noting that "CGM is a revenue opportunity for Health Care Providers," and to "Make Sure Your Health Care Providers Know This!" In describing these money-making opportunities, it identified specific Medicare reimbursement rates for patient evaluation sessions, CGMS Initiation sessions and Physician Interpretations and reports.

499. In addition to utilizing provider's specific data, Medtronic tracked trends and changes in government reimbursement that would affect their providers, and even actively participated in efforts to affect reimbursement guidelines.

500. By way of example, in December 2009, Medtronic's Senior Director of Reimbursement and Health Affairs, Jennifer Levinson, distributed to "DL NR Managed Markets and Field Sales," and later to Territory Managers, 2010 Medicare reimbursement rates and the updating of Medtronic sales materials to reflect new rates and remarked "[a]s shown in the table below, Medicare physician payments for CGM and for E/M (office visit) codes will increase in 2010."

501. By way of further example, in 2009, Heather Miller, Medtronic's Corporate Account Manager, presented a PowerPoint entitled "iPro Reimbursement & Impact to Your Territory Practices." In it, she identifies Medicare payment level reimbursements for a variety of CPT codes, advises on adherence to CMS guidelines, documentation and applicable Medicare rules, and includes comparisons between Medicare and private reimbursement rates.

502. Medtronic is well aware of the challenges associated with government payor reimbursement of its products, including Medicare's preconditions for coverage of insulin pumps. One Medtronic presentation entitled "Insulin Pump Therapy for Type II patient" referred to these coverage issues as "The Elephant in the Room."

503. Medtronic awarded Dirk Thornley Corporate Account Manager of the Year and acknowledged him in its newsletter, The Managed Market Minute, June 25, 2008 edition, for removing the "endocrinology only" restriction under Medi-Cal (California Medicaid), thus opening up additional sales to internists and other general practitioners treating Medicaid beneficiaries with Type II Diabetes, in addition to endocrinologists that primarily treat type I Diabetes patients.

504. Indeed, Medtronic unsuccessfully lobbied to get Medicare to remove the C-peptide test from the conditions for coverage of the insulin test. Decision Memo for Insulin Pump: C-Peptide Levels as a Criterion for Use (CAG-00092R) (December 17, 2004).

505. There can be no doubt that Medtronic knew and intended for healthcare providers to submit claims to government healthcare programs.

C. Medtronic Provided Consulting Services to Providers Regarding Government Healthcare Reimbursement.

506. Medtronic's knowledge is further evidenced by its utilization of reimbursement research to gain the confidence of both the providers and patients.

507. Medtronic utilized Reimbursement Guides containing Medicare reimbursement rates to assist physicians in billing for services.

508. By way of example, Medtronic's "CGM Billing and Reimbursement Guide" contains the CGM billing protocols for Professional and Personal CGM. In addition, the

guide contains a graph showing Medicare rates for common procedures, highlighting that CGM reimbursement has the highest rate of reimbursement when compared to other procedures. Medtronic further provided handouts at its "Play Big" workshop on how to utilize CGM Billing Guide to address concerns with accounts when the "main objection is concern of reimbursement."

509. By way of further example, its iPro Professional CGM Practice Guide, it contains a 30 page section on Reimbursement. The target audience was the physicians, billing specialists, office managers and other office staff involved in coding, coverage and payment collection for Professional CGM services. The readers received guidance on coding, use of modifiers, payor coverage, billing tips and tips on prior authorization and appeals processes. It includes links to each region's MAC, provides information on how to fill out CMS 1500 forms, and provides an appendix of sample forms that providers can use for letters of medical necessity and to appeal.

510. Medtronic also provided a Physician Reimbursement Guide "Fact Sheet" for the MiniMed Paradigm REAL-Time System. It also published "Medicare Insulin Pump Coverage Criteria" outlining the path for patient eligibility of Medicare benefits.

511. In addition to providing written material, through Defendant's CGM Reimbursement Hotline, Medtronic provides local Diabetes Management Consultants (DMC) who are available for questions on reimbursement in the provider's specific areas.

512. Defendants' sales representatives even drafted letters for physicians in order to obtain government healthcare coverage. For example, Relator drafted a letter on May 24, 2004 on behalf of Dr. Michaels to the Marion Polk Community Health Plan

(Oregon Medicaid) asking Medicaid to cover Medtronic's insulin pump. Relator prepared other draft letters for practices, including a letter of Medical Necessity dated October 19, 2010 for Physician Assistant John Nelson's signature for a Medicare beneficiary. Relator is not the only sales representative to have prepared draft letters for physicians to obtain government benefits; draft letters were also provided by Medtronic's corporate office.

513. In addition to personal assistance, Medtronic, in partnership with Lifescan, Inc., sponsored a special edition of the *Medical Economics* publication in May 2009, describing "How to build office efficiency and get reimbursed with Professional CGM," including sections on "Reimbursement Basics for Professional CGM" discussing Medicare reimbursement for the precise CPT codes defendants anticipate being billed.

514. Again in June 2010, Medtronic and Lifescan, Inc. sponsored a *Medical Economics* entitled, "Set Up Your Practice for Success." In the Frequently Asked Questions section of this edition, CGM Data Interpretation Billing was addressed. The publication states that, "Medicare covers Professional CGM in all 50 states but does not currently cover Personal CGM, so CPT codes 95250 and 95251 would not be billed to Medicare for Personal CGM." In addition, the article states that the 2010 Medicare national average physician payout amount for CPT code 95251 (used for billing the Professional CGM interpretation and report) is $41.50 with actual rates varying by region and describes that Medicare allowable includes the 20 percent patient co-insurance.

515. In another Medtronic-sponsored event, entitled "Beyond A1C: A New Tool for Glycemic Control" on May 12, 2010, the promotion promised that, "you will gain an

understanding of coding, reimbursement strategies, and other tips for ensuring successful CGM use in your practice.

516. Defendants' assistance extended to the patients themselves. Medtronic's main marketing brochure entitled, "The Peace of Mind You Want. The Freedom You Deserve" is provided directly to patients and is left with doctors' offices to be distributed to patients. In this promotional packet, Medtronic touts its "Insurance Processing Assistance" which includes "Medicare guideline compliance information provided to assist you in interpreting your coverage benefits." This packet also contains a "Patient Information Authorization and Assignment of Benefits" form from which Defendants collected Medicare Coverage information, including the patient's specific Medicare number.

517. In the pediatric patient packet, entitled "Your Life. Your Way," Medtronic encourages potential patients to consider 7 factors when choosing an insulin pump, including "Coverage Advocacy." Medtronic states that it continues to work with insurance companies to ensure that insulin pumps and CGM are covered by commercial and government insurance programs.

518. Medtronic filed insurance claims on behalf of patients, including claims for government sponsored insurance programs. On the Medtronic MiniMed Patient Information Sheet, patients were required to assign their insurance benefits to Defendants.

519. By way of further example, Medtronic trained its representatives on how to take inbound calls from Medicare customers, providing bullet points on what is required for current Medicare customers and for customers placing a first order.

520. Medtronic's extensive research on government healthcare reimbursement and its provision of guidelines to providers, as well as personal billing assistance to providers and patients is further evidence that Medtronic was well aware that its schemes impacted government healthcare programs.

D. Medtronic's Schemes Resulted in False Claims to Government Healthcare Programs.

521. Medtronic's schemes resulted in false claims to government healthcare programs.

522. Each and every claim resulting from illegal remuneration arrangements with providers in exchange for orders, including claims for pumps, insulin, pump supplies, and physician services, are false claims.

523. Each and every claim resulting from material misrepresentation to providers regarding the safety and effectiveness, and in turn the reasonableness and necessity, of drugs and devices, are false claims.

524. Each and every claim supported by false representations regarding the eligibility of the beneficiary for pump therapy are false claims.

525. Each and every claim for upgraded or replacements which were induced by false representations by Medtronic, but in actuality unnecessary for the government program patient, are false claims.

526. These claims violate material conditions of payment of the claim. Defendants' conduct, if known, would be capable of influencing the decision to pay these claims.

527. Notwithstanding that Medtronic knew these schemes violated material conditions of government healthcare programs, Medtronic caused false claims to be

submitted to government healthcare programs.

528. Further, Medtronic has made no effort to identify and return overpayments related to these claims.

529. Medtronic's schemes are corporately-directed and nationwide in scope.

530. Representative examples of providers targeted by these schemes have been identified supra.

531. Additionally, representative examples of individual government healthcare beneficiaries for whom claims have been made as a result of these false and fraudulent schemes have been similarly identified in paragraphs 242, 292, 367, 424, and 474.

532. Defendants' conduct has harmed federal and state healthcare programs.

VIII. Medtronic Unlawfully Retaliated Against Relator.

533. Relator was a longstanding and loyal employee of Medtronic who consistently achieved excellent sales results in the course of over six years of employment in the Company's diabetes division. He was recognized as a top performer via his promotion in June 2007 to the rank of Senior Territory Manager, his selection in June 2007 to Medtronic's President's Club, and his designation in May 2010 as a National Field Trainer in addition to the performance of his duties as a Senior Territory Manager. Relator never received anything less than a rating of "successful contributor" on his performance reviews and often achieved the higher or highest-allowed performance rating. Medtronic believed in Relator's skills and value to the company so strongly that it paid for him to get his MBA and Master's in Science and Strategic Management. Relator accomplished this while working full time as a Territory Manager and later as a Senior Territory Manager.

534. Although Relator's sales work was based in Oregon, throughout the entirety of his employment, Relator had frequent contact with MiniMed's corporate headquarters in California. Approximately twice a year, Relator brought customers to the California headquarters for special sales calls called "Customer Visits." Relator participated in multiple conference calls run from the California headquarters, including: monthly national sales calls run by Mike Gill; "Greg's Huddle" calls, which were periodic conference calls about Medtronic performance and outlook run by Gregory Meehan, then-Vice President of Sales; and product training calls run by corporate staff. Relator also conferred by telephone multiple times a day with the Diabetes Therapy Associate assigned to assist him, who was located in California.

535. As a Senior Territory Manager, Relator worked under the immediate supervision of a District Field Manager. During July 2010, Medtronic assigned Mike Ware as Relator's District Field Manager and Mr. Ware remained Relator's District Field Manager through the date of Relator's termination. Among Mr. Ware's foremost concerns as District Field Manager was his team's aggressive use of iPro clinics to enhance sales of pump therapy to MDI patients eligible for reimbursement variously through Medicare, Medicaid and private insurance in line with the marketing program described above.

536. Prior to July 2010, Relator had utilized the assistance of his DCM to handle medical aspects of the iPro clinic procedure including insertion of the iPro sensor under the patient's skin via insertion of a large needle. Relator had been outspoken in his sales district about not conducting iPro clinics and inserting needles on his own. Relator's manager at the time, Travis Allen, had accepted Relator's practice and had

not pressured him to perform the iPro clinics himself. Accordingly, Mr. Ware was aware of Relator's practice in that regard when he became Relator's District Field Manager. Beginning in July 2010, Mr. Ware directed Relator to handle the iPro procedure alone, without the assistance of his DCM who was an RN, because Medtronic wanted the sales representatives to be the main point of contact with the patients. Since Relator believed doing so constituted the performance of a medical diagnostic procedure, despite Mr. Ware's direction, he continued to have his DCM perform the procedure.

537. As District Field Manager, Mr. Ware supervised Relator's work through periodic field rides, which involved accompanying Relator on visits to the offices of physicians in his territory through whom Medtronic marketed its insulin infusion pump and other products. Relator had his first field ride with Mr. Ware on September 28 and 29, 2010, during which there were no iPro clinics scheduled, yet the primary focus of their discussions was on the performance of iPro clinics.

538. During the September 28-29, 2010, field ride, Mr. Ware directed Relator that, when he performed the iPro clinics, he needed to do them himself rather than having his DCM perform the procedures. Relator objected to this direction stating that he had no legal or business certification that qualified him to perform any medical diagnostic procedure. Disregarding Relator's concern, Mr. Ware insisted that it was necessary for Relator to perform the iPro clinics by himself – without either his DCM or physician's staff members being present – in order to maximize the opportunity to sell patients on pump therapy and simultaneously free up the physician's staff.

539. During the September 28-29, 2010, field ride, Mr. Ware also instructed Relator to show physicians Medtronic's economic model and to tell them how much

money they could make by billing for staff time during his meetings with them. Relator objected that providing physicians with a service which they did not perform but for which they could claim payment "sounded like a kickback" to the physicians. Mr. Ware responded in a visibly irritated manner and instructed Relator to follow his directions notwithstanding Relator's concerns about the legality of Mr. Ware's instructions.

540. Mr. Ware was clearly displeased with Relator's insistence that it would be improper for him to perform iPro clinics without the assistance of medical personal and his expressed concerns about engaging in a marketing scheme with physicians that improperly incentivized physicians by providing kickbacks. Consequently, at the end of the field ride, Mr. Ware gave Relator low field-ride ratings of 1 and 2 out of 5 in most categories, even though Relator had achieved top results in the district for sales of pump therapy.

541. In response to Mr. Ware's pressure on Relator to perform iPro clinics alone in order to maximize the sales of Medtronic pump therapy to MDI diabetes patients, Relator sought to memorialize Mr. Ware's instruction. By email to Mr. Ware dated October 14, 2010, Relator summarized Mr. Ware's instructions regarding Territory Managers performing iPro clinics in the respective physicians' offices on a weekly or biweekly basis indefinitely. In the email, Relator documented that Mr. Ware wanted him, as a Territory Manager, to sell iPro patients on pump therapy while he hooked up and downloaded Medtronic's sensor device and that his conducting the iPro clinics would benefit the physician by freeing up his office staff. Mr. Ware responded: "You have a solid plan. Now it is about executing on the plan."

542. Relator repeatedly expressed reservations to Mr. Ware about being

required personally to insert needles and to remove the needle leaving the glucose sensor secured under the patient's skin. Relator objected both because insertion of the needle to hook up the device is a medical procedure which he was not qualified to perform and because insertion of the needle in two of the recommended sites – the upper pubic and upper buttocks areas – posed a gross invasion of the patient's privacy, particularly when the patient was of the opposite gender, and posed a medical risk to patients. On the occasion of the first field ride and thereafter, Mr. Ware forcefully rejected Relator's concerns and directed him to do the procedures himself under threat of being fired if he did not.

543. Mr. Ware accompanied Relator on a second field ride on October 25, 2010 which involved visits to the office of Dr. Priva Krishnamurthy and to Providence Diabetes Center. Knowing that Dr. Krishnamurthy routinely permitted Medtronic to run the iPro clinics without any involvement by her staff, Relator had asked his DCM to participate in the October 25, 2010 clinic in order to handle all of the medical aspects. When Mr. Ware realized that the DCM was participating in the clinic, he strongly criticized Relator for his plan to use the DCM's assistance. Mr. Ware insisted that Relator needed to be solely responsible for conducting the iPro clinic to maximize the sales opportunities. Mr. Ware refused to allow the DCM to perform the procedure and instead required Relator to perform the invasive medical procedures. Relator complied, fearing that his job was on the line if he refused to do so. However, Relator was very uncomfortable with performing the medical procedure, especially given that he had to insert the sensor into the upper pubic area of an obese female patient. Prior to this occasion, Relator had never performed insertions on a patient.

544. Relator also held an iPro clinic at Providence Diabetes Center on October 26, 2010 that Mr. Ware attended. Because the Providence Diabetes Center did not permit Medtronic to perform the medical procedure, Mr. Ware could not force Relator to do so. Despite not conducting the iPro clinics himself, Relator successfully convinced three patients to seek pump therapy for a total of ten new patients requesting pump therapy in a two day period.

545. Mr. Ware harshly criticized Relator during the second field ride for being unwilling to examine patient databases both at Providence Hospital and in the office of Dr. John Gallen for the purpose of identifying patients who would be potential customers for pump therapy. Relator objected that reviewing the patient databases would be a HIPAA violation. Mr. Ware nevertheless responded that Relator was required to review the patient databases as directed even though Teri Martisek, the RN responsible for Providence Hospital's database, and Dr. Gallen also objected to providing Relator with access to the databases.

546. Subsequent to the second field ride, Relator continued to talk to coworkers about his opposition to Medtronic's requirement that he personally perform the iPro clinic procedure without the assistance of medical personnel. Relator learned from his DCM that another Medtronic employee had informed Mr. Ware about Relator's continued practice of utilizing the DCM to insert needles and otherwise perform the medical aspects of the iPro clinics rather than performing the medical procedures himself. Relator began to feel the adverse effects of his refusal to violate the law. Other team members began to marginalize him and stopped returning his calls and emails.

547. By email dated November 1, 2010, Mr. Ware acknowledged that Relator's performance in October 2010 was strong. He stated: "Strong close to the month! Great job."

548. Notwithstanding Relator's strong performance, Mr. Ware remained upset that Relator had involved his DCM in performing procedures at the iPro clinics and had refused to access the hospital's patient database, in clear violation of HIPAA. On November 2, 2010, Mr. Ware wrote Relator a Letter of Concern admonishing him for involving the DCM in iPro clinics. Mr. Ware reiterated that it is the responsibility of the Territory Managers "to perform and complete iPro clinics on their own." Mr. Ware also criticized Relator for his unwillingness to press Ms. Martisek at Providence Hospital for access to the hospital's patient database which he had told Mr. Ware would be a HIPAA violation. Mr. Ware issued the Letter of Concern notwithstanding Relator's objectively satisfactory performance, including that Relator continued to be a sales leader in the district and region.

549. Concerned with the impropriety of Mr. Ware's instructions, Relator contacted the FDA during November 2010 and reported his concerns regarding the manner in which Medtronic conducted iPro clinics. Relator also reported his broader concerns about Medtronic's improper sales and marketing practices, including its off label promotion of its pump and CGM sensor device; its payments and services to physicians as quid pro quo for assistance by physicians in marketing its products in relation to the iPro clinics; and its related fraudulent practices. The FDA advised Relator that his concern about being required to perform the iPro clinics himself was outside the FDA's jurisdiction, but within that of the Oregon Medical Board.

550. On December 5, 2010, Relator filed complaint number 118060 with the FDA which included substantially all of the practices referenced herein. Relator had repeatedly raised his concerns regarding the off-label practices he reported in this Complaint and detailed to coworkers in the past.

551. On January 7, 2011, Mr. Ware placed Relator on a Corrective Action Plan, in further retaliation for Relator's objections: to being required to perform the iPro clinics without participation of qualified medical personnel; to the manner in which Medtronic was providing free services to physicians in connection with the iPro clinics; and to Mr. Ware's direction that he electronically search doctors' patient databases for patients who are on MDI therapy. The Corrective Action Plan required Relator "to set up and conduct" a minimum of five iPro clinics per week upon threat of imposition of a Performance Improvement Plan and possible termination of employment.

552. On or around January 13, 2011, Relator contacted the Oregon Medical Board to report his concerns about Mr. Ware's direction that he perform medical procedures while conducting iPro clinics. Staff at the Oregon Medical Board advised Relator that the iPro procedure, involving insertion of a medical device under a patient's skin, is a medical diagnostic procedure which may only be lawfully performed by licensed medical personnel consistent with Oregon law.

553. On January 24, 2011, Relator spoke to Alicia Markety, a MiniMed Human Resources representative based in California, about the Corrective Action Plan Mr. Ware had placed him on. Ms. Markety explained that a Corrective Action Plan is typically the first step in the performance management process. She further explained that after being placed on a Corrective Action plan, an employee is typically placed on a

Performance Improvement Plan, and that at the end of the Performance Improvement Plan, if the sales goals or the expectations are not met, the employee would face termination.

554. By email of January 31, 2011, Relator informed Mr. Ware that he intended to report “all of the issues you have brought to the table with the proper internal Medtronic Corporate departments.” He further stated "it is likely and should be expected that not only will there be very few calls this week and that it is possible that entire days will be spent in conversation with Medtronic Corporate. If you have an issue with this please let me know right now so that I can address them with the respective divisions of Medtronic Corporate as I discuss my performance as well as your conduct and actions with them at length." Relator further stated, "I will expect to not receive any retaliatory emails for not having enough calls to hit the criteria for the CAP you created."

555. By email dated February 1, 2011, to Celeste Ortiz, Defendant MiniMed’s Vice President of Human Resources based in California, Relator alerted Medtronic to the fact that Mr. Ware was trying to “apply pressure on [him] and push[ing him] out of the company.” He provided a detailed refutation to the statements Mr. Ware made in Relator's Corrective Action Plan, including comprehensive data demonstrating that he was outperforming other Territory Managers in his District, none of whom were put on a Corrective Action Plan. Ms. Ortiz responded by email that evening advising Relator that she was in receipt of his email and wanted an opportunity to review the matter. She further advised Relator that she would be in touch with him later that week to follow up. By email on February 4, 2011, Ms. Ortiz informed Relator that they had “looked into” the matters he raised, but were continuing his Corrective Action Plan.

556. On February 8, 2011, the FDA visited Medtronic MiniMed corporate headquarters in Northridge, California, commencing an investigation of the practices reported by Relator through his complaint of December 5, 2010. Given Relator's vocal opposition to Medtronic's practices, which was well-known to Relator's superiors and co-workers alike, Medtronic correctly concluded that the FDA's initiation of an investigation into off-label promotion and kickbacks was precipitated by the information Relator had provided. Indeed, Relator's coworkers openly speculated that he was the source of the FDA complaint. Moreover, Medtronic had access to the records of Relator's use of his company cell phone which he used in his early efforts to make contact with the FDA in November 2010.

557. The same day that the FDA visited MiniMed and initiated its investigation into company practices, Ms. Ortiz directed Relator to work with Medtronic's legal department to address any concerns he had. Following her direction, on February 8, 2011 Relator emailed Reuben Mjaanes, Principal Legal Counsel for Medtronic, the Legal Department contact Ms. Ortiz had provided him, who is based in Minnesota.

558. On February 9, 2011, Relator sent a memorandum to Mr. Mjaanes, in which he reported that Mr. Ware had insisted at the time of his first field ride that he personally perform the iPro clinics notwithstanding that he told Mr. Ware at that time that the procedure "was not lawfully performed by a Territory Manager." He further stated his belief that the practice posed a substantial danger to public health and safety. Relator further reported that he told Mr. Ware at the same time that doing the clinics for the physicians "and then telling them that they can bill and make so much money was not right" and "sounded like a kickback to me." He reported that Mr. Ware responded

that he “needed to use the economic model to sell them on the finances of the ipro” and that he (Relator) “needed to take over so that we could convert all of their MDI patients to pump therapy.”

559. Relator further reported through the February 9, 2011 memorandum to Medtronic's Principal Legal Counsel that “[s]ince pushing back to Mike Ware during our first field ride” he had “been harassed and retaliated against” including most recently through imposition of the Corrective Action Plan. Mr. Mjaanes did not interview Relator about his allegations.

560. Instead, by email dated February 17, 2011, Mr. Mjaanes informed Relator that he and Medtronic’s Compliance had reviewed the “iPro issues [he] raised” and that “[i]n neither case, was there a finding that [he was] being retaliated against or that performance issues were not being addressed appropriately.” Upon information and belief, Medtronic failed to conduct an appropriate investigation into the matters Relator had reported.

561. On February 28, 2011, just twenty days after the FDA’s visit to Medtronic Diabetes corporate headquarters and nineteen days after Relator contacted Medtronic’s legal department, Mr. Ware and a MiniMed Human Resources representative in California telephoned Relator and informed him that he was fired. Mr. Ware stated that the reason for the termination was that Relator had not met all the provisions of the Corrective Action Plan to his complete satisfaction. Mr. Ware then noted that "more importantly," Relator's "behavior" is what led to his termination. Relator pressed for the reasons for such a decision, pointing out that his sales were better than prevailing levels for the nation as a whole. Mr. Ware responded that “we made a business decision to

terminate your employment effective immediately based on your current performance as well as and more importantly your behaviors to this point through the Corrective Action Plan." These explanations were pretextual. Aside from Relator's objections to practices that he reasonably believed violated federal and state law, including particularly those associated with conduct of the iPro clinics, Relator had not been criticized or counseled about any alleged "behavior" problems. Medtronic MiniMed officials in California participated in the decision to terminate Relator's employment and actually approved his termination.

562. Mr. Ware's treatment of Relator constituted disparate treatment. Relator's performance was objectively better than Territory Managers who were not placed on a Corrective Action Plan or terminated. Mr. Ware's treatment of Relator stood in stark contrast to his treatment of Mark Collingwood, another Territory Manager in the same district. Despite achieving similar sales numbers throughout the time period in question, Mr. Ware placed Relator on a Corrective Action Plan on January 7, 2012, but did not place Mr. Collingwood on such a plan. On February 8, 2011, after Relator had repeatedly complained that Mr. Ware had singled him out compared to similar performers, Mr. Ware also placed Mr. Collingwood on a Corrective Action Plan that was virtually identical to that of Relator's. Mr. Ware's treatment of Mr. Collingwood while he was on the plan, however, was starkly different than his treatment of Relator. Both Mr. Collingwood and Relator performed strongly while on their Corrective Action Plans, but neither was able to meet the unrealistic goals Mr. Ware had set for them in the plan. At the conclusion of Relator's plan, Medtronic terminated Relator without first placing him on a Performance Improvement Plan as was the company's standard practice. When

Mr. Collingwood reached the conclusion of his Corrective Action Plan, Mr. Ware congratulated him and told him that the Corrective Action Plan was not a disciplinary action, but rather a "management tool."

563. Almost immediately after terminating Relator's employment, Mr. Ware told Relator's former co-worker that Relator was suing Medtronic and directed the co-worker to have no contact with Relator. This statement indicates that Medtronic was aware that Relator was the source of the FDA investigation, since Medtronic could not have known about this suit until it was unsealed on August 21, 2012.

564. Defendants' conduct has caused continuing damage to Relator's reputation and career.

CLAIMS ON BEHALF OF THE UNITED STATES

Count I
Federal False Claims Act
31 U.S.C. §§ 3729(a)(1)(A), B), and (G)

565. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

566. The False Claims Act, 31 U.S.C. § 3729(a)(1)(A), (B), and (G) imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim or to an obligation to pay money to the government, or those who knowingly conceal, improperly avoid or decrease an obligation to pay money to the government.

567. Defendants knowingly and willfully violated the AKS and Stark Statute by offering and paying illegal remuneration to government healthcare program providers in

exchange for the ordering of their medical devices and supplies. Defendants knew these violations resulted in claims submitted to government healthcare programs. As a result, Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding the compliance of those claims with the AKS and Stark Statute.

568. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce government healthcare programs providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that these schemes resulted in claims submitted to government healthcare programs.

569. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that these schemes resulted in claims submitted to government healthcare programs.

570. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

571. Defendants' actions, if known, would have affected the United States and the States' decision to pay the resulting claims.

572. Defendants' actions violated material conditions of payment under government healthcare programs.

573. The resulting claims are false claims.

574. Defendants acted knowingly, as that term is used in the False Claims Act.

575. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to government healthcare programs for payment or approval, within the meaning of 31 U.S.C. § 3729(a)(1)(A).

576. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, material to a false or fraudulent claim to government healthcare programs, within the meaning of 31 U.S.C. § 3729(a)(1)(B).

577. By virtue of the acts described above, defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner. Defendants' ongoing and knowing failure to report these overpayments violates the False Claims Act, 31 U.S.C. § 3729(a)(1)(G).

578. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by the defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

579. Because the United States would not have paid for services which it knew to have been the result of illegal inducements and material misrepresentations to the ordering providers, the United States has been harmed in an amount equal to the value paid by the United States.

580. By reason of the defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

CLAIMS ON BEHALF OF THE STATES

Count II
California False Claims Act
Cal Govt Code § 12651(a) , *et seq.*

581. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

582. This is a claim for treble damages and penalties under the California False Claims Act.

583. The California False Claims Act, Cal. Gov. Code § 12651(a)(1)-(a)(2), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim.

584. Defendants knowingly presented or caused false claims to be submitted the California Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

585. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

586. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims

submitted to government healthcare programs.

587. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

588. Defendants' actions, if known, would have affected the California State Government and the State's decision to pay the resulting claims.

589. Defendants' actions violated material conditions of payment under the State's healthcare programs.

590. The resulting claims are noncovered and nonpayable and are false claims.

591. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

592. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

593. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the California State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

594. Defendants acted knowingly, as that term is used in the California False Claims Act, Cal. Gov. Code § 12650(b)(3).

595. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

596. By reason of the defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

597. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count III
California Insurance Frauds Prevention Act
California Insurance Code § 1871.7

598. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

599. This is a claim for treble damages and penalties under the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7, as amended (referred to in this Count as "the Act"). The Act provides for civil recoveries against persons who violate the provisions of the Act or the provisions of California Penal Code sections 549 or 550, including recovery of up to three times the amount of any fraudulent insurance claims, and fines of between $5,000 and $10,000 for each such claim. Cal. Ins. Code §1871.7(b).

600. Subsection (e) of Cal. Ins. Code §1871.7 provides for a *qui tam* civil action in order to create incentives for private individuals who are aware of fraud against

insurers to help disclose and prosecute the fraud. Cal. Ins. Code §1871.1(e). The *qui tam* provision was patterned after the Federal False Claims Act, 31 U.S.C. §§3729-32, and the California False Claims Act, Cal. Gov't Code §§12650 et seq.

601. Subsection (b) of Cal. Ins. Code §1871.7 provides for civil recoveries against persons who violate the provisions of Penal Code sections 549 or 550. Section 550 of the Penal Code prohibits the following activities, among others:

> (a) It is unlawful to do any of the following, or to aid, abet, solicit, or conspire with any person to do any of the following:
>
> * * * * * *
>
> (5) Knowingly prepare, make, or subscribe any writing, with the intent to present or use it, or to allow it to be presented, in support of any false or fraudulent claim.
>
> (6) Knowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit.
>
> * * * * * *
>
> (b) It is unlawful to do, or to knowingly assist or conspire with any person to do, any of the following:
>
> (1) Present or cause to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.
>
> (2) Prepare or make any written or oral statement that is intended to be presented to any insurer or any insurance claimant in connection with, or in support of or opposition to, any claim or payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information
> concerning any material fact.
>
> (3) Conceal, or knowingly fail to disclose the occurrence of, an event that affects any person's initial or continued right or entitlement to any insurance benefit or payment, or the amount of any benefit or payment to which the person is entitled.

Cal. Penal Code § 550.

602. By virtue of the acts described in this Complaint, defendants knowingly presented or caused to be presented, false or fraudulent claims for health care benefits, in violation of Penal Code §550(a).

603. Each claim for reimbursement that was a result of defendants' illegal practices represents a false or fraudulent record or statement, and a false or fraudulent claim for payment.

604. Private insurers, unaware of the falsity of the records, statements and claims made or caused to be made by defendants, paid and continue to pay the claims that would not be paid but for defendants' unlawful conduct.

605. The California State Government is entitled to receive three times the amount of each claim for compensation submitted in violation of Cal. Ins. Code §1871.7. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count IV
Colorado False Claims Act
Colo. Rev. Stat. § 25.5-4-303.5, *et seq.*

606. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

607. This is a claim for treble damages and penalties under the Colorado False Claims Act.

608. The Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-305(1)(a)-(1)(b), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to false claims.

609. Defendants knowingly presented or caused false claims to be submitted the Colorado Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare

programs.

610. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

611. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

612. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

613. Defendants' actions, if known, would have affected the Colorado State Government and the State's decision to pay the resulting claims.

614. Defendants' actions violated material conditions of payment under the State's healthcare programs.

615. The resulting claims are noncovered and nonpayable and are false claims.

616. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Colorado State Government for payment or approval.

617. By virtue of the acts described above, defendants knowingly made, used,

or caused to be made or used false records and statements, and omitted material facts, to induce the Colorado State Government to approve and pay such false and fraudulent claims.

618. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Colorado State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

619. Defendants acted knowingly, as that term is used in the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-304(3)(a).

620. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

621. By reason of the defendants' acts, the State of Colorado has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

622. Additionally, the Colorado State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count V
Connecticut False Claims Act
Conn. Publ Law 09-05

623. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

624. This is a claim for treble damages and penalties under the Connecticut False Claims Act for Medical Assistance Programs, General Statute 17.319(v) § 17b-301b, *et seq*.

625. The Connecticut False Claims Act, General Statute 17.319(v) § 17b-301b, imposes liability upon, inter alia, those who knowingly present, or cause to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval under a medical assistance program administered by the Department of Social Services, or those who knowingly make, use or cause to be made or used, a false record or statement to secure the payment or approval by the state of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services, or conspire to defraud the state by securing the allowance or payment of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services.

626. Defendants knowingly presented or caused false claims to be submitted the Connecticut Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

627. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

628. Defendants also knowingly engaged in a scheme to cause the submission

of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

629. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

630. Defendants' actions, if known, would have affected the Connecticut State Government and the State's decision to pay the resulting claims.

631. Defendants' actions violated material conditions of payment under the State's healthcare programs.

632. The resulting claims are noncovered and nonpayable and are false claims.

633. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Connecticut State Government for payment or approval.

634. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Connecticut State Government to approve and pay such false and fraudulent claims.

635. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Connecticut State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal

inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

636. Defendants acted knowingly, as that term is used in the Connecticut False Claims Act, General Statute 17.319(v) § 17b-301a.

637. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

638. By reason of the defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

639. Additionally, the Connecticut State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count VI
Delaware False Claims And Reporting Act
6 Del C. § 1201(a) , *et seq.*

640. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

641. This is a claim for treble damages and penalties under the Delaware False Claims And Reporting Act.

642. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(1)-(a)(2), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

643. Defendants knowingly presented or caused false claims to be submitted the Delaware Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

644. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

645. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

646. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

647. Defendants' actions, if known, would have affected the Delaware State Government and the State's decision to pay the resulting claims.

648. Defendants' actions violated material conditions of payment under the State's healthcare programs.

649. The resulting claims are noncovered and nonpayable and are false claims.

650. By virtue of the acts described above, defendants knowingly presented or

caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

651. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

652. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Delaware State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

653. Defendants acted knowingly, as that term is used in the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1202(3).

654. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

655. By reason of the defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

656. Additionally, the Delaware State Government is entitled to the maximum penalty of $11,000 for each and every violation alleged herein.

Count VII
District of Columbia False Claims Act, D.C. Code 2-381.01 *et seq.*

657. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

658. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.

659. The District of Columbia False Claims Act, D.C. Code § 2-381.02(a)(1)-(a)(2), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

660. Defendants knowingly presented or caused false claims to be submitted the District of Columbia's Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

661. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

662. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

663. Defendants knowingly made and caused to be made material

misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

664. Defendants' actions, if known, would have affected the District of Columbia and the District's decision to pay the resulting claims.

665. Defendants' actions violated material conditions of payment under the State's healthcare programs.

666. The resulting claims are noncovered and nonpayable and are false claims.

667. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

668. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

669. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the District of Columbia Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

670. Defendants acted knowingly, as that term is used in the District of Columbia False Claims Act, D.C. Code § 2-381.01(3).

671. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' defective laboratory tests, unnecessary treatments and surgeries, and/or illegal inducements and business practices.

672. By reason of the defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

673. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

Count VIII
Florida False Claims Act
Fla. Stat. Ann. § 68.082(2) , *et seq.*

674. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

675. This is a claim for treble damages and penalties under the Florida False Claims Act.

676. The Florida False Claims Act, Fla. Stat. § 68.082(2)(a)-(2)(b), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

677. Defendants knowingly presented or caused false claims to be submitted the Florida Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare

programs.

678. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

679. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

680. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

681. Defendants' actions, if known, would have affected the Florida State Government and the State's decision to pay the resulting claims.

682. Defendants' actions violated material conditions of payment under the State's healthcare programs.

683. The resulting claims are noncovered and nonpayable and are false claims.

684. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

685. By virtue of the acts described above, defendants knowingly made, used,

or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

686. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Florida State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

687. Defendants acted knowingly, as that term is used in the Florida False Claims Act, Fla. Stat. § 68.082(1)(c).

688. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

689. By reason of the defendants' acts, the State of Florida has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

690. Additionally, the Florida State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count IX
Georgia False Claims Act
Ga. Code Ann. § 49-4-168, *et seq.*

691. The allegations in the foregoing paragraphs are re-alleged as if fully set

forth herein.

692. This is a claim for treble damages and penalties under the Georgia False Claims Act.

693. The Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.1(a)(1)-(a)(2), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

694. Defendants knowingly presented or caused false claims to be submitted the Georgia Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

695. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

696. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

697. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and

necessity of the resulting claims.

698. Defendants' actions, if known, would have affected the Georgia State Government and the State's decision to pay the resulting claims.

699. Defendants' actions violated material conditions of payment under the State's healthcare programs.

700. The resulting claims are noncovered and nonpayable and are false claims.

701. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

702. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

703. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Georgia State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

704. Defendants acted knowingly, as that term is used in the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168(2).

705. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or

presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

706. By reason of the defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

707. Additionally, the Georgia State Government is entitled to the maximum penalty of $11,000 for each and every violation alleged herein.

Count X
Hawaii False Claims Act
Haw. Rev. Stat. § 661-21(a) , *et seq.*

708. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

709. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

710. The Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a)(1)-(a)(2), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

711. Defendants knowingly presented or caused false claims to be submitted the Hawaii Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

712. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses.

Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

713. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

714. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

715. Defendants' actions, if known, would have affected the Hawaii State Government and the State's decision to pay the resulting claims.

716. Defendants' actions violated material conditions of payment under the State's healthcare programs.

717. The resulting claims are noncovered and nonpayable and are false claims.

718. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

719. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

720. By virtue of the acts described above, defendants knowingly and

improperly avoided or decreased an obligation to transmit money or property to the Hawaii State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

721. Defendants acted knowingly, as that term is used in the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(e).

722. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

723. By reason of the defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

724. Additionally, the Hawaii State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XI
Illinois Whistleblower Reward And Protection Act
740 Ill. Comp. Stat. § 175/3(a) , *et seq.*

725. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

726. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act.

727. The Illinois False Claims Act, 740 Ill. Comp. Stat. 175/3(a)(1)(A)-(a)(1)(B), imposes liability upon, inter alia, those who knowingly cause to be presented false

claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim.

728. Defendants knowingly presented or caused false claims to be submitted the Illinois Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

729. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

730. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

731. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

732. Defendants' actions, if known, would have affected the Illinois State Government and the State's decision to pay the resulting claims.

733. Defendants' actions violated material conditions of payment under the State's healthcare programs.

734. The resulting claims are noncovered and nonpayable and are false claims.

735. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

736. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

737. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Illinois State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

738. Defendants acted knowingly, as that term is used in the Illinois False Claims Act, 740 Ill. Comp. Stat. 175/3(b)(1).

739. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

740. By reason of the defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

741. Additionally, the Illinois State Government is entitled to the maximum

penalty of $10,000 for each and every violation alleged herein.

Count XII
Illinois Insurance Claims Frauds Prevention Act
740 Ill. Comp. Stat. §92

742. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

743. This is a claim for treble damages and penalties under the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. §92.

744. Subsection 5(b) of the Illinois Insurance Claims Fraud Prevention Act provides:

> A person who violates any provision of this Act or Article 46 of the Criminal Code of 1961 shall be subject, in addition to any other penalties that may be prescribed by law, to a civil penalty of not less than $5,000 nor more than $10,000, plus an assessment of not more than 3 times the amount of each claim for compensation under a contract of insurance.

745. Article 46 of the Illinois Criminal Code, referenced in the above-quoted section, provides criminal penalties for any person who commits the offense of insurance fraud, defined in the statute as follows:

> (a) A person commits the offense of insurance fraud when he or she knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company . . . .

720 Ill. Comp. Stat. §5/46-1(a).

746. Subsection 15(a) of the Illinois Insurance Claims Fraud Prevention Act provides for a *qui tam* civil action in order to create incentives for private individuals to prosecute violations of the statute. Subsection 15(a) provides: "An interested person, including an insurer, may bring a civil action for a violation of this Act for the person and

for the State of Illinois. The action shall be brought in the name of the State." 740 Ill. Comp. Stat. §92/15(a).

747. By virtue of the conduct described in this Complaint, defendants committed the following acts, or aided and abetted the commission of the following acts, in violation of the Illinois Insurance Claims Fraud Prevention Act: knowingly obtained, attempted to obtain, and caused to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim and by causing a false claim to be made on a policy of insurance issued by an insurance company, in violation of 740 Ill. Comp. Stat. §92/5(b) and 720 Ill. Comp. Stat. §5/46-1(a).

748. As a result of such conduct, defendants has received illegal profits to which it was not entitled, at the expense of insurers and at the expense of the People of the State of Illinois, in substantial amount to be determined at trial.

749. The Illinois State Government is entitled to receive three times the amount of each claim for compensation submitted by defendants in violation of 740 Ill. Comp. Stat. §92. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XIII
Indiana False Claims And Whistleblower Protection Act
IC 5-11-5.5-2(b) , *et seq.*

750. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

751. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

752. Indiana law, Ind. Code § 5-11-5.5-2(b)(1)-(b)(2), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to obtain payment or approval of false claims.

753. Defendants knowingly presented or caused false claims to be submitted the Indiana Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

754. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

755. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

756. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

757. Defendants' actions, if known, would have affected the Indiana State Government and the State's decision to pay the resulting claims.

758. Defendants' actions violated material conditions of payment under the State's healthcare programs.

759. The resulting claims are noncovered and nonpayable and are false claims.

760. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

761. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

762. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Indiana State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

763. Defendants acted knowingly, as that term is defined in Ind. Code § 5-11-5.5-1(4).

764. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

765. By reason of the defendants' acts, the State of Indiana has been

damaged, and continues to be damaged, in substantial amount to be determined at trial.

766. Additionally, the Indiana State Government is entitled to a civil penalty of at least $5,000 for each and every violation alleged herein.

Count XIV
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. § 437 *et seq.*

767. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

768. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Programs Integrity Law.

769. The Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46:438.3(A)-(B), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements material false claims.

770. Defendants knowingly presented or caused false claims to be submitted the Louisiana Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

771. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

772. Defendants also knowingly engaged in a scheme to cause the submission

of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

773. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

774. Defendants' actions, if known, would have affected the Louisiana State Government and the State's decision to pay the resulting claims.

775. Defendants' actions violated material conditions of payment under the State's healthcare programs.

776. The resulting claims are noncovered and nonpayable and are false claims.

777. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

778. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

779. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Louisiana State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal

inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

780. Defendants acted knowingly, as that term is used in the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46:437.3(11).

781. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

782. By reason of the defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

783. Additionally, the Louisiana State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XV
Maryland False Health Claims Act
Md. HEALTH-GENERAL Code Ann. § 2-601, *et seq.*

784. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

785. This is a claim for treble damages and penalties under the Maryland False Health Claims Act.

786. The Maryland False Health Claims Act, Md. Code. Ann., Health-Gen. § 2-602(a)(1)-(a)(2), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements material to false claims.

787. Defendants knowingly presented or caused false claims to be submitted

the Maryland Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

788. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

789. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

790. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

791. Defendants' actions, if known, would have affected the Maryland State Government and the State's decision to pay the resulting claims.

792. Defendants' actions violated material conditions of payment under the State's healthcare programs.

793. The resulting claims are noncovered and nonpayable and are false claims.

794. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Maryland State Government

for payment or approval.

795. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Maryland State Government to approve and pay such false and fraudulent claims.

796. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Maryland State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

797. Defendants acted knowingly, as that term is used in the Maryland False Health Claims Act, Md. Code. Ann., Health-Gen. § 2-601(f).

798. The Maryland State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

799. By reason of the defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

800. Additionally, the Maryland State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XVI
Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 § 5B *et seq*

801. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

802. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

803. The Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5B(1)-(2), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to obtain payment or approval of a claim.

804. Defendants knowingly presented or caused false claims to be submitted the Massachusetts Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

805. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

806. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

807. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

808. Defendants' actions, if known, would have affected the Massachusetts State Government and the State's decision to pay the resulting claims.

809. Defendants' actions violated material conditions of payment under the State's healthcare programs.

810. The resulting claims are noncovered and nonpayable and are false claims.

811. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval.

812. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts State Government to approve and pay such false and fraudulent claims.

813. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Massachusetts State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

814. Defendants acted knowingly, as that term is used in the Massachusetts

False Claims Act, Mass. Gen. Laws ch. 12, § 5A(a).

815. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

816. By reason of the defendants' acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

817. Additionally, the Massachusetts State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XVII
Michigan Medicaid False Claims Act
Mich. Comp. Laws. § 400.601 *et seq*

818. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

819. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

820. The Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.607(1), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval.

821. Defendants knowingly presented or caused false claims to be submitted the Michigan Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

822. Defendants also knowingly engaged in misleading and/or false

promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

823. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

824. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

825. Defendants' actions, if known, would have affected the Michigan State Government and the State's decision to pay the resulting claims.

826. Defendants' actions violated material conditions of payment under the State's healthcare programs.

827. The resulting claims are noncovered and nonpayable and are false claims.

828. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

829. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent

claims.

830. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Michigan State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

831. Defendants acted knowingly, as that term is used in the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.602(f).

832. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

833. By reason of the defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

834. Additionally, the Michigan State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XVIII
Minnesota False Claims Act
Minn. Stat. § 15C.01 *et seq*

835. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

836. This is a claim for treble damages and penalties under the Minnesota Medicaid False Claims Act.

837. Minnesota Law, Minn. Stat. § 15C.02(a)(1)-(a)(2), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

838. Defendants knowingly presented or caused false claims to be submitted the Minnesota Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

839. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

840. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

841. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

842. Defendants' actions, if known, would have affected the Minnesota State Government and the State's decision to pay the resulting claims.

843. Defendants' actions violated material conditions of payment under the State's healthcare programs.

844. The resulting claims are noncovered and nonpayable and are false claims.

845. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Minnesota State Government for payment or approval.

846. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Minnesota State Government to approve and pay such false and fraudulent claims.

847. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Minnesota State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

848. Defendants acted knowingly, as that term is defined in Minn. Stat. § 15C.01(3).

849. The Minnesota State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

850. By reason of the defendants' acts, the State of Minnesota has been

damaged, and continues to be damaged, in substantial amount to be determined at trial.

851. Additionally, the Minnesota State Government is entitled to the maximum penalty of $11,000 for each and every violation alleged herein.

Count XIX
Montana False Claims Act
Mont. Code Ann. § 17-8-401 *et seq.*

852. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

853. This is a claim for treble damages and penalties under the Montana False Claims Act.

854. The Montana False Claims Act, Mont. Code Ann. § 17-8-403(1)(a)-(1)(b), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

855. Defendants knowingly presented or caused false claims to be submitted the Montana Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

856. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

857. Defendants also knowingly engaged in a scheme to cause the submission

of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

858. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

859. Defendants' actions, if known, would have affected the Montana State Government and the State's decision to pay the resulting claims.

860. Defendants' actions violated material conditions of payment under the State's healthcare programs.

861. The resulting claims are noncovered and nonpayable and are false claims.

862. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval.

863. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

864. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Montana State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal

inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

865. Defendants acted knowingly, as that term is used in the Montana False Claims Act, Mont. Code Ann. § 17-8-402(4)(a).

866. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

867. By reason of the defendants' acts, the State of Montana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

868. Additionally, the Montana State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XX
Nevada False Claims Act
Nev. Rev. Stat. Ann. § 357.040(1), *et seq.*

869. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

870. This is a claim for treble damages and penalties under the Nevada False Claims Act.

871. Nevada Law, Nev. Rev. Stat. § 357.040(1)(a)-(1)(b), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to obtain payment or approval of false claims.

872. Defendants knowingly presented or caused false claims to be submitted

the Nevada Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

873. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

874. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

875. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

876. Defendants' actions, if known, would have affected the Nevada State Government and the State's decision to pay the resulting claims.

877. Defendants' actions violated material conditions of payment under the State's healthcare programs.

878. The resulting claims are noncovered and nonpayable and are false claims.

879. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for

payment or approval.

880. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

881. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Nevada State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

882. Defendants acted knowingly, as that term is defined in Nev. Rev. Stat. § 357.040(1)(a)-(1)(b).

883. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

884. By reason of the defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

885. Additionally, the Nevada State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XXII
New Jersey False Claims Act
N.J. Stat. § 2A:32C-1 *et seq.*

886. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

887. This is a claim for treble damages and penalties under the New Jersey False Claims Act.

888. The New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-3(a)-(b), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

889. Defendants knowingly presented or caused false claims to be submitted the New Jersey Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

890. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

891. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

892. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

893. Defendants' actions, if known, would have affected the New Jersey State Government and the State's decision to pay the resulting claims.

894. Defendants' actions violated material conditions of payment under the State's healthcare programs.

895. The resulting claims are noncovered and nonpayable and are false claims.

896. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

897. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

898. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the New Jersey State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

899. Defendants acted knowingly, as that term is used in the New Jersey False

Claims Act, N.J. Stat. Ann. § 2A:32C-2.

900. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

901. By reason of the defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

902. Additionally, the New Jersey State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XXIII
New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.* and New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-1 *et seq.*

903. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

904. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act and the New Mexico Fraud Against Taxpayers Act.

905. The New Mexico Medicaid, N.M. Stat. Ann. § 27-14-4(A) and (C), imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims to the New Mexico Medicaid program, and those who make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

906. The New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-3(A)(1) and (2) imposes liability upon, inter alia, those who knowingly present or cause

to be presented false claims, and those who make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

907. Defendants knowingly presented or caused false claims to be submitted the New Mexico Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

908. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

909. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

910. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

911. Defendants' actions, if known, would have affected the New Mexico State Government and the State's decision to pay the resulting claims.

912. Defendants' actions violated material conditions of payment under the State's healthcare programs.

913. The resulting claims are noncovered and nonpayable and are false claims.

914. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

915. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

916. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the New Mexico State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

917. Defendants acted knowingly, as that term is used in the New Mexico False Claims Act, § 44-9-2(C).

918. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

919. By reason of the defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

920. Additionally, the New Mexico State Government is entitled to the

maximum civil penalty of $10,000 for each and every violation alleged herein.

Count XXIV
New York False Claims Act
N.Y. State Fin. § 187 *et seq.*

921. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

922. This is a claim for treble damages and penalties under the New York False Claims Act.

923. The New York False Claims Act, N.Y. State Fin. Law § 189(1)(a)-(1)(b), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements material to false claims.

924. Defendants knowingly presented or caused false claims to be submitted the New York Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

925. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

926. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims

submitted to government healthcare programs.

927. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

928. Defendants' actions, if known, would have affected the New York State Government and the State's decision to pay the resulting claims.

929. Defendants' actions violated material conditions of payment under the State's healthcare programs.

930. The resulting claims are noncovered and nonpayable and are false claims.

931. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

932. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

933. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the New York State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

934. Defendants acted knowingly, as that term is used in the New York False Claims Act, N.Y. State Fin. Law § 188(3).

935. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

936. By reason of the defendants' acts, the State of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

937. Additionally, the New York State Government is entitled to the maximum penalty of $12,000 for each and every violation alleged herein.

Count XXV
North Carolina False Claims Act
N.C. Gen. Stat. § 1-605 *et seq.*

938. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

939. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

940. The North Carolina False Claims Act, N.C. Gen. Stat. § 1-607(a)(1)-(a)(2), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements material to false claims.

941. Defendants knowingly presented or caused false claims to be submitted the North Carolina Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government

healthcare programs.

942. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

943. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

944. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

945. Defendants' actions, if known, would have affected the North Carolina State Government and the State's decision to pay the resulting claims.

946. Defendants' actions violated material conditions of payment under the State's healthcare programs.

947. The resulting claims are noncovered and nonpayable and are false claims.

948. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina State Government for payment or approval.

949. By virtue of the acts described above, defendants knowingly made, used,

or caused to be made or used false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

950. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the North Carolina State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

951. Defendants acted knowingly, as that term is used in the North Carolina False Claims Act, N.C. Gen. Stat. § 1-606(4).

952. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

953. By reason of the defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

954. Additionally, the North Carolina State Government is entitled to the maximum penalty of $11,000 for each and every violation alleged herein.

Count XXVI
Oklahoma Medicaid False Claims Act
63 Okl. St. § 5053

955. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

956. This is a claim for treble damages and penalties under the Oklahoma Medicaid False Claims Act.

957. The Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1(B)(1)-(B)(2), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

958. Defendants knowingly presented or caused false claims to be submitted the Oklahoma Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

959. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

960. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

961. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and

necessity of the resulting claims.

962. Defendants' actions, if known, would have affected the Oklahoma State Government and the State's decision to pay the resulting claims.

963. Defendants' actions violated material conditions of payment under the State's healthcare programs.

964. The resulting claims are noncovered and nonpayable and are false claims.

965. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

966. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

967. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Oklahoma State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

968. Defendants acted knowingly, as that term is used in the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1(A)(1).

969. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or

presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

970. By reason of the defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

971. Additionally, the Oklahoma State Government is entitled to the maximum civil penalty of $10,000 for each and every violation alleged herein.

Count XXVII
Rhode Island False Claims Act
R.I. Gen. Laws § 9-1.1-1 *et seq.*

972. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

973. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.

974. The Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-3(a)(1)-(a)(2), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

975. Defendants knowingly presented or caused false claims to be submitted the Rhode Island Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

976. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses.

Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

977. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

978. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

979. Defendants' actions, if known, would have affected the Rhode Island State Government and the State's decision to pay the resulting claims.

980. Defendants' actions violated material conditions of payment under the State's healthcare programs.

981. The resulting claims are noncovered and nonpayable and are false claims.

982. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

983. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

984. By virtue of the acts described above, defendants knowingly and

improperly avoided or decreased an obligation to transmit money or property to the Rhode Island State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

985. Defendants acted knowingly, as that term is used in the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-3(b).

986. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

987. By reason of the defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

988. Additionally, the Rhode Island State Government is entitled to civil penalties for each and every violation alleged herein.

Count XXVIII
Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)

989. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

990. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Act.

991. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. §71-5-182(a)(1)-(a)(2), imposes liability upon, inter alia, those who knowingly cause to be

presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

992. Defendants knowingly presented or caused false claims to be submitted the Tennessee Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

993. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

994. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

995. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

996. Defendants' actions, if known, would have affected the Tennessee State Government and the State's decision to pay the resulting claims.

997. Defendants' actions violated material conditions of payment under the

State's healthcare programs.

998. The resulting claims are noncovered and nonpayable and are false claims.

999. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

1000. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

1001. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Tennessee State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

1002. Defendants acted knowingly, as that term is used in the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182.

1003. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

1004. By reason of the defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

1005. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XXIX
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. § 36.002

1006. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

1007. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

1008. Texas law, Tex. Hum. Res. Code Ann. § 36.002(1)-(13) imposes liability upon, inter alia, those who knowingly cause to be made false statements or misrepresentations of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized.

1009. Defendants knowingly presented or caused false claims to be submitted the Texas Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

1010. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

1011. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims

submitted to government healthcare programs.

1012. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

1013. Defendants' actions, if known, would have affected the Texas State Government and the State's decision to pay the resulting claims.

1014. Defendants' actions violated material conditions of payment under the State's healthcare programs.

1015. The resulting claims are noncovered and nonpayable and are false claims.

1016. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

1017. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

1018. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Texas State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

1019. Defendants acted knowingly, as that term is used in Tex. Hum. Res. Code Ann. § 36.0011(a).

1020. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

1021. By reason of the defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

1022. Additionally, the Texas State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XXX
Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.1 *et seq.*

1023. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

1024. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

1025. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(1)-(A)(2), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to get false claims paid or approved.

1026. Defendants knowingly presented or caused false claims to be submitted the Virginia Medicaid program by engaging in illegal kickback schemes. Defendants

knew that the schemes resulted in claims submitted to government healthcare programs.

1027. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

1028. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

1029. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

1030. Defendants' actions, if known, would have affected the Virginia State Government and the State's decision to pay the resulting claims.

1031. Defendants' actions violated material conditions of payment under the State's healthcare programs.

1032. The resulting claims are noncovered and nonpayable and are false claims.

1033. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval.

1034. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Virginia State Government to approve and pay such false and fraudulent claims.

1035. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Virginia State Government. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

1036. Defendants acted knowingly, as that term is used in the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(C).

1037. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

1038. By reason of the defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

1039. Additionally, the Virginia State Government is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

Count XXXI
Wisconsin False Claims For Medical Assistance Act
Wis. Stat § 20.931 *et seq.*

1040. The allegations in the foregoing paragraphs are re-alleged as if fully set

forth herein.

1041. This is a claim for treble damages and penalties under the Wisconsin False Claims For Medical Assistance Act.

1042. The Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931(2)(a)-(2)(b), imposes liability upon, inter alia, those who knowingly cause to be presented false claims for payment or approval, and those who knowingly make or use, or cause to be made or used, false records or statements to obtain approval or payment of false claims.

1043. Defendants knowingly presented or caused false claims to be submitted the Wisconsin Medicaid program by engaging in illegal kickback schemes. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

1044. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and/or noncovered and payable uses. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

1045. Defendants also knowingly engaged in a scheme to cause the submission of unnecessary claims for upgraded or replacement medical devices for government healthcare program beneficiaries. Defendants knew that the schemes resulted in claims submitted to government healthcare programs.

1046. Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding compliance with

government healthcare program requirements, including the reasonableness and necessity of the resulting claims.

1047. Defendants' actions, if known, would have affected the Wisconsin State Government and the State's decision to pay the resulting claims.

1048. Defendants' actions violated material conditions of payment under the State's healthcare programs.

1049. The resulting claims are noncovered and nonpayable and are false claims.

1050. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin Government for payment or approval.

1051. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the State of Wisconsin to approve and pay such false and fraudulent claims.

1052. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the State of Wisconsin. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner.

1053. Defendants acted knowingly, as that term is defined in Wis. Stat. § 20.931(1)(d).

1054. The State of Wisconsin, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by

defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

1055. By reason of the defendants' acts, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

1056. Additionally, the State of Wisconsin is entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

CLAIMS ON BEHALF OF RELATOR ADAM WITKIN PERSONALLY

Count XXXIII
Federal False Claims Act
31 U.S.C. § 3730(h)

1057. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

1058. This is a claim pursuant to 31 U.S.C. § 3730(h) for relief from defendants' retaliatory actions as necessary to make Relator whole for being subjected to unlawful discharge from employment and otherwise subjected to unlawful discrimination and retaliation as a consequence of lawful acts done by him to report what he reasonably believed were false claims for payment from federal payors resulting from Defendants' marketing practices and in furtherance of a possible action for violation of the federal False Claims Act.

1059. As alleged above, Relator engaged in lawful acts in furtherance of efforts to stop one or more violations of 31 U.S.C. § 3729.

1060. Relator's lawful acts include but are not limited to:

a. his filing of complaint no. 118060 with the United States Food and Drug Administration on December 5, 2011;

b. his objection to instructions issued by Mike Ware relating to the marketing of Medtronic products in connection with iPro clinics on September 28 and 29, 2010 and thereafter;

c. his email to Mike Ware dated January 31, 2011 indicating his intention to bring the iPro issues to the attention of the proper departments of Medtronic and

d. his memorandum sent to Medtronic's corporate legal department on February 9, 2011 reporting what he reasonably believed were violations of the federal health care Anti-Kickback statute.

1061. Defendants were on notice of Relator's objections to corporate practices, including improper sales and marketing practices, which were in violation of federal statutory requirements governing government healthcare claims.

1062. Because of Relator's lawful acts (a-d) above, Relator was subjected to discrimination in the terms and conditions of his employment, including but not limited to the following: Medtronic issued a Letter of Concern to Relator, placed him on a Corrective Action Plan, subjected him to other discrimination and retaliation, and ultimately, terminated his employment effective February 28, 2011. These acts constituted retaliation for Relator's lawful acts in reporting, attempting to stop, and acting in furtherance of other efforts to stop what he reasonably believed were actions by Medtronic in violation of the FCA and federal Anti-Kickback statute and in furtherance of a possible qui tam action.

1063. As a direct and proximate result of the foregoing, Relator has lost the benefits and privileges of employment, and has suffered continuing damage to his

reputation and career. Relator is entitled to all relief necessary to make him whole.

Count XXXIV
Wrongful Termination in Violation of Common Law of Oregon

1064. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

1065. This is a claim for relief from wrongful termination in violation of fundamental public policy pursuant to the common law of Oregon. The common law of Oregon prohibits an employer in Oregon from discharging an individual from at-will employment for reporting what the employee reasonably believes to be a violation of a statute, law or regulation where the employee makes the report pursuant to an important public duty or for refusing to perform what the employee reasonably believes to be an unlawful act.

1066. Through the filing of complaint no. 118060 with the United States Food and Drug Administration on December 5, 2011; his oral objections to Mike Ware of September 28 and 29, 2010 and thereafter; his email to Mr. Ware dated January 31, 2011 indicating his intention to bring the iPro clinic issues to the attention of the proper departments of Medtronic and his memorandum sent February 9, 2011 to Medtronic's corporate legal department, Relator reported what he reasonably believed to be violations of federal law and the law of Oregon that implicate fundamental public policy including:

a. Medtronic's unlawful off-label marketing practices in violation of the federal Food Drug & Cosmetic Act as set forth *supra* and reported through Relator's complaint no. 118060 to the Food and Drug Administration;

b. Medtronic's unlawful practices in violation of the federal health care

Anti-Kickback statute as set forth *supra* and reported through Relator's complaint no. 118060 to the Food and Drug Administration;

c. Medtronic's practices regarding the conduct of iPro clinics as reported in Relator's memorandum sent February 9, 2011 to Medtronic's corporate legal department;

d. Medtronic's requirement that he and other sales personnel, not licensed pursuant to Oregon law, nevertheless perform medical diagnostic procedures constituting the practice of medicine in connection with the conduct of iPro Clinics without being licensed as required by ORS §§ 677.085, .495, .520.

1067. In making the foregoing reports, Relator acted pursuant to important public duties to prevent and remedy fraud on Medicare and other government health care payors and to protect public health and safety by calling attention to and seeking to prevent the unauthorized practice of medicine.

1068. Medtronic's action in discharging Relator, effective February 28, 2011, was in retaliation for reports made in fulfillment of public duties and for his refusal to engage in what he reasonably believed would be acts violating the federal Food Drug & Cosmetic Act, the federal Anti-Kickback Statute, the federal False Claims Act and the law of Oregon prohibiting performance of medical diagnostic procedures by unlicensed personnel.

1069. As a direct and proximate result of the foregoing, Relator has lost the benefits and privileges of employment, and has suffered continuing damage to his reputation and career. Relator is entitled to all relief necessary to make him whole.

1070. Defendants engaged in conduct described above in deliberate disregard

of the rights of others, which constitutes wanton misconduct.

Count XXXV
Discrimination for Whistleblowing in Violation of ORS § 659A.199

1071. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

1072. This is a claim for relief pursuant to ORS § 659A.199, which makes it "an unlawful employment practice for an employer to discharge, or in any manner discriminate or retaliate against and employee for the reason that the employee has in good faith reported information that the employee believes is evidence of a violation of a state or federal law, rule or regulation." The provision states further that the remedies thereby provided are in addition to any common law or other remedy that may be available. ORS § 659A.885 authorizes a civil action for violation of designated provisions including § 659A.199.

1073. Through his verbal objections to Mike Ware on September 28 and 29, 2010 and thereafter, his submission of a complaint to the FDA on December 5, 2010, his email dated January 31, 2011 to Mike Ware, and his memorandum sent February 9, 2011 to Medtronic's corporate legal department, Relator reported what he reasonably and in good faith believed amounted to violations of the federal Food Drug & Cosmetic Act, the federal Anti-Kickback Statute, the federal False Claims Act and the law of Oregon prohibiting performance of medical diagnostic procedures by unlicensed personnel.

1074. Medtronic discriminated and retaliated against Relator in violation of ORS § 659A.199 when it: issued to Relator the Letter of Concern, placed Relator on a Corrective Action Plan; subjected Relator to other discrimination and retaliation, and

terminated his employment.

1075. As a direct and proximate result of the foregoing, Relator has lost the benefits and privileges of employment, and has suffered continuing damage to his reputation and career. Relator is entitled to all relief necessary to make him whole.

1076. Defendants engaged in conduct described above in deliberate disregard of the rights of others, which constitutes wanton misconduct.

Count XXXVI
Wrongful Termination in Violation of Common Law of California

1077. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

1078. This is a claim for relief from wrongful termination in violation of fundamental public policy pursuant to the common law of California. The common law of California prohibits an employer in California from discharging an individual from at-will employment for reporting what the employee reasonably believes to be a violation of a statute, law or regulation that implicates fundamental public policy or for refusing to perform what the employee reasonably believes to be an unlawful act.

1079. Through the filing of complaint no. 118060 with the United States Food and Drug Administration on December 5, 2011; his oral objections to Mike Ware of September 28 and 29, 2010 and thereafter; his email to Mr. Ware dated January 31, 2011 indicating his intention to bring the iPro clinic issues to the attention of the proper departments of Medtronic and his memorandum sent February 9, 2011 to Medtronic's corporate legal department, Relator reported what he reasonably believed to be violations of federal law and the law of Oregon that implicate fundamental public policy including:

a. Medtronic's unlawful off-label marketing practices in violation of the federal Food Drug & Cosmetic Act as set forth *supra* and reported through Relator's complaint no. 118060 to the Food and Drug Administration;

b. Medtronic's unlawful practices in violation of the federal healthcare Anti- Kickback statute, federal False Claims Act, California False Claims Act, and California Insurance Frauds Prevention Act as set forth *supra* and reported through Relator's complaint no. 118060 to the Food and Drug Administration;

c. Medtronic's practices regarding the conduct of iPro clinics as reported in Relator's memorandum sent February 9, 2011 to Medtronic's corporate legal department in violation of California's Unfair Competition Law, Cal. Bus & Prof. Code §§ 17200 et seq.;

d. Medtronic's requirement that he and other sales personnel, not licensed pursuant to Oregon law, nevertheless perform medical diagnostic procedures constituting the practice of medicine in connection with the conduct of iPro Clinics without being licensed as required by ORS §§ 677.085, .495, .520.

1080. Medtronic's action in discharging Relator, effective February 28, 2011, was in retaliation for reports made in fulfillment of public duties and for his refusal to engage in what he reasonably believed would be acts violating the federal Food Drug & Cosmetic Act, the federal Anti-Kickback Statute, the federal False Claims Act and the law of Oregon prohibiting performance of medical diagnostic procedures by unlicensed personnel.

1081. As a direct and proximate result of the foregoing, Relator has lost the benefits and privileges of employment, and has suffered continuing damage to his

reputation and career. Relator is entitled to all relief necessary to make him whole.

1082. Defendants engaged in the conduct described above with malice – meaning that Defendants' conduct was meant to cause injury to Relator or was despicable conduct which was carried on by the Defendants with a willful and conscious disregard of the rights or safety of others, or with oppression, or fraud.

PRAYER

WHEREFORE, Relator prays for judgment against the defendants as follows:

1. that defendants cease and desist from violating 31 U.S.C. § 3729 *et seq.*, and the counterpart provisions of the state statutes set forth above;

2. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 31 U.S.C. § 3729;

3. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of California has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code § 12651(a);

4. that this Court enter judgment against defendants in an amount equal to three times the amount of each claim for compensation submitted by defendant in violation of Cal. Ins. Code §1871.7(b), plus a civil penalty of $10,000 for each violation of Cal. Ins. Code §1871.7(b);

5. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Colorado has sustained because of

defendants' actions, plus a civil penalty of $10,000 for each violation of Colo. Rev. Stat. § 25.5-4-303.5, *et seq.*;

6. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Conn. Pub. Law 09-05;

7. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. § 1201(a);

8. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 1-1188.14(a);

9. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Fla. Stat. Ann. § 68.082(2);

10. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Georgia Code Ann. § 49-4-168;

11. that this Court enter judgment against defendants in an amount equal to

three times the amount of damages the State of Hawaii has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. § 661-21(a);

12. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. § 175/3(a);

13. that this Court enter judgment against defendants in an amount equal to three times the amount of each claim for compensation submitted by defendants in violation of 740 Ill. Comp. Stat. § 92, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. § 92;

14. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Ind. Code § 5-11-5.5 *et seq.*;

15. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. § 437 *et seq.*;

16. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Maryland has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Md. HEALTH-GENERAL Code Ann. § 2-601 *et seq.*;

17. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 § 5B *et seq.*;

18. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Mich. Comp. Laws § 400.601 *et seq.*;

19. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Minnesota has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Minn. Stat. § 15C.01 *et seq.*;

20. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Montana has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Mont. Code Ann. § 17-8-401 *et seq.*;

21. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. § 357.040(1);

22. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of defendants' actions, plus civil penalties for each violation of N.J. Stat. § 2A:32C-1 *et*

seq.;

23. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of defendants' actions, plus civil penalties for each violation of N.M. Stat. Ann. § 27-14-4 *et seq.* and N.M. Stat. Ann. § 44-9-1 *et seq.*;

24. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New York has sustained because of defendants' actions, plus civil penalties for each violation of N.Y. State Fin. § 187 *et seq.*;

25. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of N.C. Gen. Stat. § 1-605 *et seq*;

26. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of defendants' actions, plus civil penalties for each violation of 63 Okla. St. § 5053 *et seq.*;

27. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of defendants' actions, plus civil penalties for each violation of R.I. Gen. Laws § 9-1.1-1 *et seq.*;

28. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Tenn. Code

Ann. § 71-5-182(a)(1);

29. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. § 36.002;

30. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Virginia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. § 8.01-216.3(a);

31. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of the Wis. Stat. § 20.931 *et seq.*;

32. that Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

33. that the Court enter judgment against the defendants for the States', Commonwealths' and District's costs of this action;

34. that this Court enter judgment against defendants pursuant to 31 U.S.C. § 3730(h) including an order reinstating Relator to his employment with the full seniority and benefits he would have had but for his retaliatory discharge and awarding him two times the amount of his back pay and compensation for special damages including litigation costs and reasonable attorney's fees;

35. that this Court enter judgment against defendants for wrongful termination in violation of the common law of Oregon with awards of compensatory and punitive damages;

36. that this Court enter judgment against defendants for unlawful discrimination and retaliation in violation of ORS § 659A.199 and order injunctive relief including but not limited to Relator's reinstatement with back pay, and additionally award compensatory and punitive damages, and attorney's fees and legal expenses;

37. that this Court enter judgment against defendants for wrongful termination in violation of the common law of California with awards of compensatory and punitive damages;

38. that Relator be awarded all costs of this action, including attorneys' fees and expenses;

39. that the United States Government, the respective States and Relators receive all relief, both at law and in equity, to which they may reasonably appear entitled.

40. that Relator recover such other relief as the Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: February 11, 2013

Respectfully submitted,

/s/ Jennifer M. Verkamp
Jennifer M. Verkamp
Frederick M. Morgan, Jr.
MORGAN VERKAMP LLC
700 Walnut Street, Suite 400
Cincinnati, Ohio 45202
jverkamp@morganverkamp.com
rmorgan@morganverkamp.com

David Rich (BBO# 634275)
Christopher Weld (BBO# 522230)
TODD & WELD LLP
28 State Street, 31st Floor Boston, MA 02109
drich@toddweld.com
cweld@toddweld.com
Tel: (617) 720-2626
Fax: (617) 227-5777

Peter W. Chatfield
PHILLIPS & COHEN LLP
2000 Massachusetts Ave., NW
Washington, DC. 20036
Telephone: (202) 833-4567
Fax: (202) 833-1815
peter@phillipsandcohen.com

Larry P. Zoglin
PHILLIPS & COHEN LLP
131 Steuart St., Suite 501
San Francisco, CA 94105
Telephone: (415) 836-9000
Fax: (415) 836-9001
lpz@pcsf.com

Debra S. Katz
Daniel B. Edelman
Katz Marshall & Banks LLP
1718 Connecticut Ave. NW, 6th Floor
Washington, D.C. 20009

Telephone: (202) 299-1140
Fax: (202) 299-1148
katz@kmblegal.com
edelman@kmblegal.com

Attorneys for Qui Tam Plaintiff/Relator Adam Witkin

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was sent via the Court's electronic filing system, and served to all counsel of record on February 11, 2013.

/s/ Jennifer M. Verkamp
Jennifer M. Verkamp